

US3542061 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:04:57

All time stamps listed in this document are displayed in GMT

US3542061

Form: Participant Creation

Data signed: (b) (4) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

[Participant ID](#)

US3542061

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

US3542061

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="checkbox"/> Male <input checked="" type="checkbox"/>
Ethnicity	Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input checked="" type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/>
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) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542061

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	ELEVATED CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN MAY 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2007
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2007
Start Year (derived)	2007
Stop Month and Year (derived)	MAY 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 16:51:32

Generated On: 10 Jun 2021 08:04:57

Condition	BOTOX (LEFT UNDER EYE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:21
Height (xxx.x)	74 in
Weight (xxx.x)	196 lb
BMI (xxx.x)	25.21753 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Dec 2020 16:15:20

Generated On: 10 Jun 2021 08:04:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

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

RETIRED/MILITARY

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) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Oct 2020 02:23:45

Generated On: 10 Jun 2021 08:04:57

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188345

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) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

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) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:21
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 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) 18 Dec 2020 16:15:20

Generated On: 10 Jun 2021 08:04:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 27 Aug 2020 15:43:21

Generated On: 10 Jun 2021 08:04:57

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 10:20 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 10:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	09:48 (24 HR)
Collection date and time (derived)	26 AUG 2020 09:48

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	26 AUG 2020 09:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

26 AUG 2020 10:56

PC Open Date & Time

26 AUG 2020 10:40

PC Close Date & Time

26 AUG 2020 13:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	26 AUG 2020 21:36
PC Open Date & Time	26 AUG 2020 14:05
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

27 AUG 2020 18:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

28 AUG 2020 20:34

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

29 AUG 2020 18:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 23:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:50

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

26 AUG 2020 10:57

PC Open Date & Time

26 AUG 2020 10:40

PC Close Date & Time

26 AUG 2020 13:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

26 AUG 2020 21:31

PC Open Date & Time

26 AUG 2020 14:05

PC Close Date & Time

27 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

27 AUG 2020 18:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

28 AUG 2020 20:34

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

29 AUG 2020 18:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

30 AUG 2020 23:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

31 AUG 2020 18:50

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

01 SEP 2020 21:59

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 10:58
PC Open Date & Time	26 AUG 2020 10:40
PC Close Date & Time	26 AUG 2020 13:10

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:32
PC Open Date & Time	26 AUG 2020 14:05
PC Close Date & Time	27 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:10
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3514

EAB) (1725)

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:36
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3514

EAB) (1725)

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:41
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 23:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

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 ☒

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 18:51
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

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 ☒

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EAB) (1725)

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:00
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 02 SEP 2020 21:56

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 SEP 2020 23:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

05 SEP 2020 00:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:12

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 00:25

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 21:53

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:24

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 13:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 SEP 2020 21:56

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 03 SEP 2020 23:33

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 00:22

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 21:12

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 SEP 2020 00:25

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 SEP 2020 21:53

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 SEP 2020 19:24

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 SEP 2020 09:35

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 SEP 2020 13:28

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 SEP 2020 17:32

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 14 SEP 2020 13:25

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 21:54

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 SEP 2020 16:14

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 23:59

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 00:12

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 17:49

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 SEP 2020 00:28

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 SEP 2020 02:17

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 02 SEP 2020 21:57

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

03 SEP 2020 23:33

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 21:57
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 23:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 00:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 21:12
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 00:25
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 21:54
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 19:24
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 09:35
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 13:28
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 17:32
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 13:25
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 21:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 16:14
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 23:59
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 00:12
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 17:50
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 00:28
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 02:17
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3542061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Sep 2020 04:53:18

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 04:53:18

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Dec 2020 16:15:20

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 04:53:18

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Sep 2020 15:18:53

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Sep 2020 15:18:53

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Sep 2020 03:11:05

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Sep 2020 04:18:13

Generated On: 10 Jun 2021 08:04:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	07:40 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 07:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Sep 2020 04:18:13

Generated On: 10 Jun 2021 08:04:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Sep 2020 03:11:05

Generated On: 10 Jun 2021 08:04:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Sep 2020 15:18:53

Generated On: 10 Jun 2021 08:04:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 SEP 2020

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

Treatment Date and Time (derived) 23 SEP 2020 08:24

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

US3542061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Sep 2020 03:11:05

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	07:55 (24 HR)
Collection date and time (derived)	23 SEP 2020 07:55

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Sep 2020 03:11:05

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:56	23 SEP 2020 07:56
Nasopharyngeal Swab 2	No		

US3542061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:18:13

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

23 SEP 2020 09:04

PC Open Date & Time

23 SEP 2020 08:44

PC Close Date & Time

23 SEP 2020 11:14

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	24 SEP 2020 00:00
PC Open Date & Time	23 SEP 2020 12:09
PC Close Date & Time	24 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 22:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 00:29

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

27 SEP 2020 00:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 16:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 00:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 09:05

PC Open Date & Time

23 SEP 2020 08:44

PC Close Date & Time

23 SEP 2020 11:14

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

24 SEP 2020 00:01

PC Open Date & Time

23 SEP 2020 12:09

PC Close Date & Time

24 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

24 SEP 2020 22:40

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 00:30

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 00:08

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 16:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

29 SEP 2020 00:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 09:05
PC Open Date & Time	23 SEP 2020 08:44
PC Close Date & Time	23 SEP 2020 11:14

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 00:02
PC Open Date & Time	23 SEP 2020 12:09
PC Close Date & Time	24 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:40
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:30
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 00:08
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 16:13
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

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 ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 OCT 2020 03:39

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 01 OCT 2020 20:35

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 OCT 2020 23:22

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 03:40

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

01 OCT 2020 03:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	30 SEP 2020 12:00
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PC Close Date & Time	01 OCT 2020 11:59
----------------------	-------------------

PC Time stamp	01 OCT 2020 03:40
---------------	-------------------

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 03:40
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 23:22
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3542061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Dec 2020 16:15:20

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 15:29:10

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Dec 2020 16:15:20

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 02:23:45

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 10:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

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.

US3542061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	20 OCT 2020 10:40

US3542061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:33:32

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 23:59:42
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 15:28:05
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 00:02:15
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 00:55:52
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 11:41:31
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 13:52:42

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 00:49:50
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 22:48:31

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 22:17:50
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 20:47:19
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 15:28:52
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 12:38:25

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:57:45

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:16:15

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 FEB 2021 20:02:33
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 00:34:20

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 00:33:05
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 01:42:41

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 16:24:13
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 00:03:11
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 16:43:12

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 12:01:20

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 00:26:33

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 17:45:27

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 00:22:12
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 21:56:30

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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°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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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22 FEB 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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01 MAR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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08 MAR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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15 MAR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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22 MAR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>

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

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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16 AUG 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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27 SEP 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

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01 NOV 2022 23:59

US3542061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:04:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	03 MAR 2021 14:17:16

US3542061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Nov 2020 04:10:31

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Nov 2020 04:10:31

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 27 Dec 2020 22:58:41

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 27 Dec 2020 22:58:41

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Jan 2021 18:11:08

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Jan 2021 18:11:07

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:25:01

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:25:01

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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 _____

US3542061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	

US3542061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

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.

US3542061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3542061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 17:32:25

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 17:33:03

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 17:33:03

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542061

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:04:57

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3542061

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:04:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542061

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

Form: Visit Date

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3542061

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:40:25

Generated On: 10 Jun 2021 08:04:57

Date of updated informed consent (dd MMM yyyy)	07 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	07 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3542061

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

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

US3542061

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 JAN 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 10:28
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 JAN 2021
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 11:09
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

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

Form: Physical Examination

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 JAN 2021

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

US3542061

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

Form: Exposure

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 07 JAN 2021

What was the treatment time? (00:00-23:59) 10:39 (24 HR)

Treatment Date and Time (derived) 07 JAN 2021 10:39

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

US3542061

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	07 JAN 2021 10:32

US3542061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00 - 23:59)	10:35
Collection Date and Time (derived)	07 JAN 2021 10:35

US3542061

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

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:41:44

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Jan 2021 02:40:52

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Jan 2021 02:40:52

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:25
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	11:22 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 11:22
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3542061

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3542061

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 04 FEB 2021

What was the treatment time? (00:00-23:59) 10:52 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 10:52

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

US3542061

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 01:52:19

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:01:07

Generated On: 10 Jun 2021 08:04:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:01:07

Generated On: 10 Jun 2021 08:04:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542061

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 01:12:54

Generated On: 10 Jun 2021 08:04:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Mar 2021 01:12:54

Generated On: 10 Jun 2021 08:04:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542061

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 01:12:54

Generated On: 10 Jun 2021 08:04:57

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.

US3542061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 01:12:54

Generated On: 10 Jun 2021 08:04:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 MAR 2021
Collection time (00:00-23:59)	11:42 (24 HR)
Collection date and time (derived)	08 MAR 2021 11:42

US3542061

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	10:23 (24 HR)
AE start date and time (derived)	26 AUG 2020 10:23
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 AUG 2020
End time (00:00-23:59)	10:38 (24 HR)
AE End Date and Time (derived)	26 AUG 2020 10:38
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID

Adverse event

JOINT ACHES, GENERALIZED

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)

27 AUG 2020

Start time (00:00-23:59)

08:00 (24 HR)

AE start date and time (derived)

27 AUG 2020 08:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 SEP 2020

End time (00:00-23:59)

23:59 (24 HR)

AE End Date and Time (derived)

19 SEP 2020 23:59

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID

Adverse event

BODY ACHES (GENERALIZED)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 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)

07 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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID

Adverse event

DIAPHORESIS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 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)

07 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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID

Adverse event

WORSENER RIGHT
NEPHROLITHIASIS

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)

09 JAN 2021

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 ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

UNBLINDED AND RECEIVED
FIRST DOSE OF MRNA-1273 ON
07 JAN 2021, THEN PT WAS
ADMITTED 9-FEB TO 9-FEB-2021
AT WALTER REED MEDICAL
CENTER. HE UNDERWENT
NEPHROLITHOTOMY AND
RIGHT URETERAL STENT
PLACEMENT ON 9-FEB-2021. HE
WAS DISCHARGED HOME ON
9-FEB-2021. HE HAS BEEN
TAKING OXYCODONE, MOTRIN
AND TYLENOL FOR
POST-PROCEDURE SYMPTOMS.
MEDICAL RECORDS OBTAINED
AND FAXED TO MODERNA
SAFETY.

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	21:00 (24 HR)
AE start date and time (derived)	26 AUG 2020 21:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 SEP 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	11 SEP 2020 23:59
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (11)

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	USA-US084-2021-MRNA-1273-P30 1000010
Adverse event	ACUTE PANCREATITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 APR 2021
Hospital Discharge Date (dd MMM yyyy)	16 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (12)

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 02 May 2021 21:15:39

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PARTICIPANT WAS ADMITTED TO AN OUTSIDE HOSPITAL ON 08APR2021 FOR MEDICAL MANAGEMENT OF ACUTE PANCREATITIS (SYMPTOMS STARTED ON 06APR2021). HOSPITAL DISCHARGE RECORDS WERE RECEIVED ON 22APR2021. PARTICIPANT WAS DIAGNOSED WITH ACUTE PANCREATITIS DUE TO TYPICAL EPIGASTRIC PAIN RADIATING POSTERIORLY ASSOCIATED WITH ELEVATED LIPASE 3X UPPER LIMIT OF NORMAL. ABDOMINAL ULTRASOUND PERFORMED ON 09APR2021 WAS UNREMARKABLE AND CT ABDOMEN ON 08APR2021 DID NOT REVEAL ANY POTENTIAL CAUSE OF PANCREATITIS (NORMAL APPEARING PANCREAS, GALLBLADDER AND BILIARY TREE). EGD SHOWED SMALL GASTRIC ULCER AND MULTIPLE HEALING ULCERS. RESPONDED TO CONSERVATIVE MANAGEMENT (PAIN MANAGEMENT WITH OXYCODONE AND INITIATION OF PANTOPRAZOLE). DISCHARGE HOME WAS ON 16APR2021. THERE ARE NO RECORDS OF COVID-19 TESTING BEING DONE.

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	WORSENING OF PROSTATE CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 02 May 2021 21:15:39

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

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	PEPTIC ULCER DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 02 May 2021 21:15:39

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

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

AEID	
Adverse event	GROIN ABSCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 02 May 2021 21:15:39

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Sep 2020 21:26:22

Generated On: 10 Jun 2021 08:04:57

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication CASODEX

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:14:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:14:30

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Name of Medication LUPRON

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 JUL 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication LOTREL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:14:30

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Name of Medication MYRBETRIQ

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication ELEVATED CHOLESTEROL

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication PRE-PROCEDURE INFECTION
PROPHYLAXIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:14:30

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Name of Medication ETOMIDATE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 18

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NEPHROLITHOTOMY / STENT PLACEMENT
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication SUCCINYLCHOLINE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHOTOMY / STENT
PLACEMENT

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF VITAMIN D DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF VITAMIN C DEFICIENCY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication LUPRON

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF PROSTATE
CANCER

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication NORVASC

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication PEPTIC ULCER DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 14:14:30

Generated On: 10 Jun 2021 08:04:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 17:25:01

Generated On: 10 Jun 2021 08:04:57

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 18:15:09

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 FEB 2021	NEPHROLITHOTOMY AND RIGHT URETERAL STENT PLACEMENT	Adverse Event	
12 APR 2021	GROIN ABSCESS INCISION AND DRAINAGE	Adverse Event	
09 APR 2021	ABDOMINAL ULTRASOUND	Adverse Event	
08 APR 2021	ABDOMINAL CT	Adverse Event	
11 APR 2021	ESOPHAGOGASTRODUODENOSC OPY	Adverse Event	

US3542061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:04:57

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

US3542061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:04:57

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 ☐

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 18:41:07

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 18:41:07

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/FEB/2021 16:45
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

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 18:41:07

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/FEB/2021 13:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Mar 2021 18:41:07

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:01
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

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 11:51
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

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/APR/2021 17:27
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

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/APR/2021 12:02
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

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 02 May 2021 21:15:39

Generated On: 10 Jun 2021 08:04:57

SAEID	USA-US084-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/APR/2021 15:21
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

US3542061 (Prod: George Washington University)

US3542061

Form: Participant Creation

Generated On: 10 Jun 2021 08:04:57

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'US3542061'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:31:14

US3542061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:56:46

US3542061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:31:15

US3542061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:56:46

US3542061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'SCRN'	System	26 Aug 2020 13:56:46

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:31:16

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '69'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'YEARS'	System	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '69'	System	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Male (M)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05
	(b) (4)	

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05
	(b) (4)	

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:05

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered '26 Aug 2020'	(b) (4) Elissa Malkin (b) (4) (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Aug 2020'	System	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2020'	System	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Amendment 3 (3)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered empty.	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:57:02

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:31:15

US3542061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'l'	System	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:04:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:50:18

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:42
Data point term sent to Coder	System	27 Aug 2020 17:52:26
User entered 'prostate cancer'	Taylor Ladson (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2019'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2019'	System	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2019'	System	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:51:50

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:43
Data point term sent to Coder	System	27 Aug 2020 17:52:27
User entered 'type 2 diabetes'	Taylor Ladson (b) (4)	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 17:52:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Ladson (b) (4)	27 Aug 2020 17:52:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Aug 2020 17:52:01
	Taylor Ladson (b) (4)	27 Aug 2020 17:52:01
	(b) (4)	

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2015'	System	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2015'	System	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:01

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:43
Data point term sent to Coder	System	27 Aug 2020 17:52:27
User entered 'hypertension'	Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2000'	System	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2000'	System	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:22

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Investigations, HLGt: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:48
Data point term sent to Coder	System	27 Aug 2020 17:53:28
User entered 'elevated cholesterol'	Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2000'	System	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2000'	System	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:52:35

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:46
Data point term sent to Coder System	Taylor Ladson (b) (4)	27 Aug 2020 17:53:28
User entered 'myocardial infarction'	(b) (4)	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un May 2007'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User closed query 'Per DM CLR: Please review the status of this MH as this condition is not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 03:30:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
Query 'Per DM CLR: Please review the status of this MH as this condition is not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'End date added.' (Site from DM).	David Diemert (b) (4)	16 Oct 2020 21:16:12
Signature has been broken.	David Diemert (b) (4)	16 Oct 2020 21:16:05
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4)	16 Oct 2020 21:16:05
User opened query 'Per DM CLR: Please review the status of this MH as this condition is not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:18:20
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 21:16:05
	(b) (4)	
User entered 'un May 2007' reason for change: New Information	David Diemert (b) (4)	16 Oct 2020 21:16:05
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	27 Aug 2020 17:53:05
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'May 2007'	System	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2007'	System	27 Aug 2020 17:53:05

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'May 2007'	System	16 Oct 2020 21:16:05
User entered empty.	System	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2007'	System	16 Oct 2020 21:16:05
User entered empty.	System	27 Aug 2020 17:53:05

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:48
Data point term sent to Coder	System	27 Aug 2020 17:53:29
User entered 'coronary artery disease'	Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2007'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2007'	System	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2007'	System	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:53:21

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:43:55
Data point term sent to Coder	System	27 Aug 2020 17:54:30
User entered 'overactive bladder'	Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un Aug 2020'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Aug 2020'	System	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2020'	System	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	27 Aug 2020 17:53:35

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:47:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:47:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 21:18:58
Data point term sent to Coder	System	16 Oct 2020 21:18:54
User entered 'Seasonal allergies'	David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
User entered 'un UNK 2010'	(b) (4) David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 21:18:58
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2010'	System	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2010'	System	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	16 Oct 2020 21:17:58

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 12:24:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 12:24:43
Data point term sent to Coder	System	23 Mar 2021 12:23:53
User entered 'Nephrolithiasis'	David Diemert (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 15:15:53
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered empty.	System	23 Mar 2021 12:23:09

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 12:03:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 12:03:13
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
Data point term sent to Coder	(b) (4)	25 Mar 2021 17:21:49
User entered 'Botox (Left Under Eye'	System (b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:32
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2017'	System	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2017'	System	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'Jan 2017'	System	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '2017'	System	25 Mar 2021 17:20:50

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '09:21'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered '26 Aug 2020 09:21'	System	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '74' in	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42
DataPoint set to visible.	(b) (4) System	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '196' lb	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42
DataPoint set to visible.	(b) (4) System	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
Amendment Manager: User entered '25.21753'	System	17 Sep 2020 00:03:14
User entered '25.2'	System	27 Aug 2020 17:47:42
DataPoint set to visible.	System	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'kg/m2'	System	27 Aug 2020 17:47:42
DataPoint set to visible.	System	26 Aug 2020 13:57:09

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42
	(b) (4)	

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'bpm'	System	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'breaths/min'	System	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'mmHg'	System	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User entered 'mmHg'	System	27 Aug 2020 17:47:42

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34

US3542061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34

US3542061

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:25:14
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:25:14
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:47:46
	(b) (4)	

US3542061

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:25:14
User entered '26 Aug 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:25:14
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:47:46
	(b) (4)	

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	31 Aug 2020 18:46:40
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:48:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Retired/military' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	31 Aug 2020 18:46:40
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:48:48
	(b) (4)	

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Folder: Screening

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Generated On: 10 Jun 2021 08:04:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:57:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:48

US3542061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	26 Aug 2020 14:34:33

US3542061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered '26 Aug 2020'	Elissa Malkin (b) (4)	26 Aug 2020 14:34:33

US3542061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:43:21
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	26 Aug 2020 14:34:33

US3542061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'VISIT1'	System	26 Aug 2020 14:34:33

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:43:21
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:35:16

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:43:21
User entered '188345'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:35:16

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:43:21
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 13:35:16

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:46:50

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:46:50

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:46:50

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:46:50

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:46:50

US3542061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:23:45
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	13 Oct 2020 19:25:42
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 07:59:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:59:34

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '09:21'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '26 Aug 2020 09:21'	System	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '98.3' F	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '66'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'bpm'	System	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '16'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'breaths/min'	System	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '123'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '76'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:48:14

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '10:54'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '26 Aug 2020 10:54'	System	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '98.3' F	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered empty.	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '69'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'bpm'	System	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '16'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'breaths/min'	System	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '135'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '85'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	27 Aug 2020 17:49:30

US3542061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:22:44
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:22:44
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:49:39
	(b) (4)	

US3542061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:22:44
User entered empty; reason for change New Information	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:22:44
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:49:39
	(b) (4)	

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered empty.	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered empty.	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered '26 Aug 2020'	Elissa Malkin (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered '10:20'	(b) (4) Elissa Malkin (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '26 Aug 2020 10:20'	System	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:43:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'ONCE'	System	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 14:35:04

US3542061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:49:59

US3542061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:59

US3542061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '09:48'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:59

US3542061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '26 Aug 2020 09:48'	System	27 Aug 2020 17:49:59

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '26 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered '09:50'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '26 Aug 2020 09:50'	System	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered empty.	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered empty.	System	27 Aug 2020 17:50:10

US3542061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:49:45

US3542061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	27 Aug 2020 17:49:45

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:55:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '59fe4721-8d8e-4866-9dde-bcd9cb51e4ce' User entered 'Yes (Y)'	System	26 Aug 2020 14:56:04
	System	26 Aug 2020 14:56:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:55:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '59fe4721-8d8e-4866-9dde-bcd9cb51e4ce' User entered '98.3'	System	26 Aug 2020 14:56:04
	System	26 Aug 2020 14:56:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:55:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '59fe4721-8d8e-4866-9dde-bcd9cb51e4ce'	System	26 Aug 2020 14:56:04
User entered 'No (N)'	System	26 Aug 2020 14:56:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:56:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '59fe4721-8d8e-4866-9dde-bcd9cb51e4ce' User entered '26 Aug 2020 10:56'	System	26 Aug 2020 14:56:04
	System	26 Aug 2020 14:56:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 10:40'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 13:10'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:36:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4079fe93-7f74-480e-8f02-80120b797b70'	System	27 Aug 2020 01:36:52
User entered 'Yes (Y)'	System	27 Aug 2020 01:36:52

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:36:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4079fe93-7f74-480e-8f02-80120b797b70' User entered '97.8'	System	27 Aug 2020 01:36:52
	System	27 Aug 2020 01:36:52

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:36:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4079fe93-7f74-480e-8f02-80120b797b70'	System	27 Aug 2020 01:36:52
User entered 'No (N)'	System	27 Aug 2020 01:36:52

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:36:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4079fe93-7f74-480e-8f02-80120b797b70'	System	27 Aug 2020 01:36:52
User entered '26 Aug 2020 21:36'	System	27 Aug 2020 01:36:52

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 14:05'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 2'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:03:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd26cd7b0-af15-4b82-ace3-ad95f02d884a' User entered 'Yes (Y)'	System	27 Aug 2020 22:03:56
	System	27 Aug 2020 22:03:56

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:03:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd26cd7b0-af15-4b82-ace3-ad95f02d884a' User entered '98.3'	System	27 Aug 2020 22:03:56
	System	27 Aug 2020 22:03:56

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:03:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd26cd7b0-af15-4b82-ace3-ad95f02d884a'	System	27 Aug 2020 22:03:56
User entered 'No (N)'	System	27 Aug 2020 22:03:56

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:03:54', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd26cd7b0-af15-4b82-ace3-ad95f02d884a' User entered '27 Aug 2020 18:03'	System	27 Aug 2020 22:03:56
	System	27 Aug 2020 22:03:56

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 3'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:33:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '328dac81-d2c0-4649-8c02-b1cf8d9c0579' User entered 'Yes (Y)'	System	29 Aug 2020 00:34:07
	System	29 Aug 2020 00:34:07

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:33:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '328dac81-d2c0-4649-8c02-b1cf8d9c0579' User entered '98.3'	System	29 Aug 2020 00:34:07
	System	29 Aug 2020 00:34:07

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:33:56', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '328dac81-d2c0-4649-8c02-b1cf8d9c0579'	System	29 Aug 2020 00:34:07
User entered 'No (N)'	System	29 Aug 2020 00:34:07

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '328dac81-d2c0-4649-8c02-b1cf8d9c0579'	System	29 Aug 2020 00:34:07
User entered '28 Aug 2020 20:34'	System	29 Aug 2020 00:34:07

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 4'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:39:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ab788312-9a57-4a45-805f-5f5f628702e1' User entered 'Yes (Y)'	System	29 Aug 2020 22:39:45
	System	29 Aug 2020 22:39:45

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:39:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ab788312-9a57-4a45-805f-5f5f628702e1' User entered '98.3'	System	29 Aug 2020 22:39:45
	System	29 Aug 2020 22:39:45

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:39:39', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ab788312-9a57-4a45-805f-5f5f628702e1' User entered 'No (N)'	System	29 Aug 2020 22:39:45
	System	29 Aug 2020 22:39:45

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:39:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ab788312-9a57-4a45-805f-5f5f628702e1' User entered '29 Aug 2020 18:39'	System	29 Aug 2020 22:39:45
	System	29 Aug 2020 22:39:45

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 5'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:02:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fccb8dec-392d-4f79-a150-10a4927765c9'	System	31 Aug 2020 03:02:51
User entered 'Yes (Y)'	System	31 Aug 2020 03:02:51

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:02:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fccb8dec-392d-4f79-a150-10a4927765c9' User entered '97.6'	System	31 Aug 2020 03:02:51
	System	31 Aug 2020 03:02:51

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:02:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fccb8dec-392d-4f79-a150-10a4927765c9'	System	31 Aug 2020 03:02:51
User entered 'No (N)'	System	31 Aug 2020 03:02:51

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:02:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fccb8dec-392d-4f79-a150-10a4927765c9'	System	31 Aug 2020 03:02:51
User entered '30 Aug 2020 23:02'	System	31 Aug 2020 03:02:51

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 6'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:49:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'dc31b81c-6c8b-4ff5-a47d-900a7486cf54'	System	31 Aug 2020 22:50:08
User entered 'Yes (Y)'	System	31 Aug 2020 22:50:08

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:49:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'dc31b81c-6c8b-4ff5-a47d-900a7486cf54' User entered '97.8'	System	31 Aug 2020 22:50:08
	System	31 Aug 2020 22:50:08

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'dc31b81c-6c8b-4ff5-a47d-900a7486cf54'	System	31 Aug 2020 22:50:08
User entered 'No (N)'	System	31 Aug 2020 22:50:08

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'dc31b81c-6c8b-4ff5-a47d-900a7486cf54'	System	31 Aug 2020 22:50:08
User entered '31 Aug 2020 18:50'	System	31 Aug 2020 22:50:08

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 7'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:26', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c6fd8c73-9cf6-434a-ab5d-7cc15c58590d' User entered 'Yes (Y)'	System	02 Sep 2020 01:58:39
	System	02 Sep 2020 01:58:39

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c6fd8c73-9cf6-434a-ab5d-7cc15c58590d' User entered '98.3'	System	02 Sep 2020 01:58:39
	System	02 Sep 2020 01:58:39

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c6fd8c73-9cf6-434a-ab5d-7cc15c58590d'	System	02 Sep 2020 01:58:39
User entered 'No (N)'	System	02 Sep 2020 01:58:39

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c6fd8c73-9cf6-434a-ab5d-7cc15c58590d' User entered '01 Sep 2020 21:58'	System	02 Sep 2020 01:58:39
	System	02 Sep 2020 01:58:39

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:56:10', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '21af0de9-72aa-485a-8abd-54f58e64b761' User entered 'None (1)'	System	26 Aug 2020 14:57:09
	System	26 Aug 2020 14:57:09

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:56:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '21af0de9-72aa-485a-8abd-54f58e64b761'	System	26 Aug 2020 14:57:09
User entered 'No (N)'	System	26 Aug 2020 14:57:09

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:56:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '21af0de9-72aa-485a-8abd-54f58e64b761' User entered 'No (N)'	System	26 Aug 2020 14:57:09
	System	26 Aug 2020 14:57:09

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '21af0de9-72aa-485a-8abd-54f58e64b761'	System	26 Aug 2020 14:57:09
User entered 'None (1)'	System	26 Aug 2020 14:57:09

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:08', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '21af0de9-72aa-485a-8abd-54f58e64b761' User entered '26 Aug 2020 10:57'	System	26 Aug 2020 14:57:09
	System	26 Aug 2020 14:57:09

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 10:40'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 13:10'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:30:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6d9f1273-482b-4493-a942-29f5a8dbc822'	System	27 Aug 2020 01:31:32
User entered 'None (1)'	System	27 Aug 2020 01:31:32

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:30:56', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6d9f1273-482b-4493-a942-29f5a8dbc822'	System	27 Aug 2020 01:31:32
User entered 'No (N)'	System	27 Aug 2020 01:31:32

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:31:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6d9f1273-482b-4493-a942-29f5a8dbc822'	System	27 Aug 2020 01:31:32
User entered 'No (N)'	System	27 Aug 2020 01:31:32

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:31:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6d9f1273-482b-4493-a942-29f5a8dbc822'	System	27 Aug 2020 01:31:32
User entered 'None (1)'	System	27 Aug 2020 01:31:32

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:31:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6d9f1273-482b-4493-a942-29f5a8dbc822'	System	27 Aug 2020 01:31:32
User entered '26 Aug 2020 21:31'	System	27 Aug 2020 01:31:32

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 14:05'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 2'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:04:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bd16af04-90e9-4fcb-9293-e1a0cf65d9b5'	System	27 Aug 2020 22:07:55
User entered 'None (1)'	System	27 Aug 2020 22:07:55

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:04:55', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bd16af04-90e9-4fcb-9293-e1a0cf65d9b5'	System	27 Aug 2020 22:07:55
User entered 'No (N)'	System	27 Aug 2020 22:07:55

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:07:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bd16af04-90e9-4fcb-9293-e1a0cf65d9b5'	System	27 Aug 2020 22:07:55
User entered 'No (N)'	System	27 Aug 2020 22:07:55

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:07:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bd16af04-90e9-4fcb-9293-e1a0cf65d9b5'	System	27 Aug 2020 22:07:55
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 22:07:55

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:07:53', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bd16af04-90e9-4fcb-9293-e1a0cf65d9b5'	System	27 Aug 2020 22:07:55
User entered '27 Aug 2020 18:07'	System	27 Aug 2020 22:07:55

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 3'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:18', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5694faea-1d31-4cd8-a59e-ec69e2ff9c05'	System	29 Aug 2020 00:34:59
User entered 'None (1)'	System	29 Aug 2020 00:34:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:21', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5694faea-1d31-4cd8-a59e-ec69e2ff9c05'	System	29 Aug 2020 00:34:59
User entered 'No (N)'	System	29 Aug 2020 00:34:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5694faea-1d31-4cd8-a59e-ec69e2ff9c05'	System	29 Aug 2020 00:34:59
User entered 'No (N)'	System	29 Aug 2020 00:34:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5694faea-1d31-4cd8-a59e-ec69e2ff9c05'	System	29 Aug 2020 00:34:59
User entered 'None (1)'	System	29 Aug 2020 00:34:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:34:57', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5694faea-1d31-4cd8-a59e-ec69e2ff9c05'	System	29 Aug 2020 00:34:59
User entered '28 Aug 2020 20:34'	System	29 Aug 2020 00:34:59

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 4'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '2a3791de-d09f-4fbf-92b1-6db0b0e538ee' User entered 'None (1)'	System	29 Aug 2020 22:40:25
	System	29 Aug 2020 22:40:25

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:03', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '2a3791de-d09f-4fbf-92b1-6db0b0e538ee' User entered 'No (N)'	System	29 Aug 2020 22:40:25
	System	29 Aug 2020 22:40:25

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '2a3791de-d09f-4fbf-92b1-6db0b0e538ee'	System	29 Aug 2020 22:40:25
User entered 'No (N)'	System	29 Aug 2020 22:40:25

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '2a3791de-d09f-4fbf-92b1-6db0b0e538ee'	System	29 Aug 2020 22:40:25
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 22:40:25

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:22', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '2a3791de-d09f-4fbf-92b1-6db0b0e538ee' User entered '29 Aug 2020 18:40'	System	29 Aug 2020 22:40:25
	System	29 Aug 2020 22:40:25

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 5'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:02:58', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ec4433f9-f660-4a5a-bd86-edc5218f4a94'	System	31 Aug 2020 03:03:14
User entered 'None (1)'	System	31 Aug 2020 03:03:14

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ec4433f9-f660-4a5a-bd86-edc5218f4a94'	System	31 Aug 2020 03:03:14
User entered 'No (N)'	System	31 Aug 2020 03:03:14

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ec4433f9-f660-4a5a-bd86-edc5218f4a94'	System	31 Aug 2020 03:03:14
User entered 'No (N)'	System	31 Aug 2020 03:03:14

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:10', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ec4433f9-f660-4a5a-bd86-edc5218f4a94'	System	31 Aug 2020 03:03:14
User entered 'None (1)'	System	31 Aug 2020 03:03:14

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ec4433f9-f660-4a5a-bd86-edc5218f4a94' User entered '30 Aug 2020 23:03'	System	31 Aug 2020 03:03:14
	System	31 Aug 2020 03:03:14

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 6'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:16', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4233f264-29c8-4ba4-bced-cd0fcb2f365e'	System	31 Aug 2020 22:50:50
User entered 'None (1)'	System	31 Aug 2020 22:50:50

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4233f264-29c8-4ba4-bced-cd0fcb2f365e' User entered 'No (N)'	System	31 Aug 2020 22:50:50
	System	31 Aug 2020 22:50:50

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4233f264-29c8-4ba4-bced-cd0fcb2f365e'	System	31 Aug 2020 22:50:50
User entered 'No (N)'	System	31 Aug 2020 22:50:50

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4233f264-29c8-4ba4-bced-cd0fcb2f365e'	System	31 Aug 2020 22:50:50
User entered 'None (1)'	System	31 Aug 2020 22:50:50

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4233f264-29c8-4ba4-bced-cd0fcb2f365e'	System	31 Aug 2020 22:50:50
User entered '31 Aug 2020 18:50'	System	31 Aug 2020 22:50:50

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 7'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6f61c01a-4c22-4c16-ad15-13519a0fa679' User entered 'None (1)'	System	02 Sep 2020 01:59:10
	System	02 Sep 2020 01:59:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6f61c01a-4c22-4c16-ad15-13519a0fa679' User entered 'No (N)'	System	02 Sep 2020 01:59:10
	System	02 Sep 2020 01:59:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6f61c01a-4c22-4c16-ad15-13519a0fa679' User entered 'No (N)'	System	02 Sep 2020 01:59:10
	System	02 Sep 2020 01:59:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:58:55', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6f61c01a-4c22-4c16-ad15-13519a0fa679'	System	02 Sep 2020 01:59:10
User entered 'None (1)'	System	02 Sep 2020 01:59:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:59:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6f61c01a-4c22-4c16-ad15-13519a0fa679' User entered '01 Sep 2020 21:59'	System	02 Sep 2020 01:59:10
	System	02 Sep 2020 01:59:10

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:26', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered 'None (0)'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:57:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8'	System	26 Aug 2020 14:58:03
User entered 'No (N)'	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T10:58:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4717cac4-55e4-49a9-a057-f076974a8af8' User entered '26 Aug 2020 10:58'	System	26 Aug 2020 14:58:03
	System	26 Aug 2020 14:58:03

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 10:40'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 13:10'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:31:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'None (0)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'Some interference with activity (2)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'None (0)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'None (0)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'None (0)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'None (0)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered 'No (N)'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-26T21:32:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c611685d-32ad-405a-aa6c-693bbbdd298e' User entered '26 Aug 2020 21:32'	System	27 Aug 2020 01:32:49
	System	27 Aug 2020 01:32:49

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Aug 2020 14:05'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 2'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:08:03', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84'	System	27 Aug 2020 22:10:05
User entered 'No interference with activity (1)'	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:08:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84'	System	27 Aug 2020 22:10:05
User entered 'Some interference with activity (2)'	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:08:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84' User entered 'None (0)'	System	27 Aug 2020 22:10:05
	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:09:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84'	System	27 Aug 2020 22:10:05
User entered 'No interference with activity (1)'	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:09:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84' User entered 'None (0)'	System	27 Aug 2020 22:10:05
	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:09:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84' User entered 'None (0)'	System	27 Aug 2020 22:10:05
	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:09:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84'	System	27 Aug 2020 22:10:05
User entered 'No (N)'	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-27T18:10:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3da5c570-ffd0-45af-a4a2-9591991d1e84'	System	27 Aug 2020 22:10:05
User entered '27 Aug 2020 18:10'	System	27 Aug 2020 22:10:05

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 3'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b'	System	29 Aug 2020 00:36:08
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b'	System	29 Aug 2020 00:36:08
User entered 'Some interference with activity (2)'	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:18', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b' User entered 'None (0)'	System	29 Aug 2020 00:36:08
	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b'	System	29 Aug 2020 00:36:08
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b' User entered 'None (0)'	System	29 Aug 2020 00:36:08
	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b' User entered 'None (0)'	System	29 Aug 2020 00:36:08
	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:35:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b' User entered 'No (N)'	System	29 Aug 2020 00:36:08
	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-28T20:36:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b4f697-8cc4-4c0e-83f7-d387d5ade42b' User entered '28 Aug 2020 20:36'	System	29 Aug 2020 00:36:08
	System	29 Aug 2020 00:36:08

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 4'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261'	System	29 Aug 2020 22:41:28
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:40:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261'	System	29 Aug 2020 22:41:28
User entered 'Some interference with activity (2)'	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261' User entered 'None (0)'	System	29 Aug 2020 22:41:28
	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261'	System	29 Aug 2020 22:41:28
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261' User entered 'None (0)'	System	29 Aug 2020 22:41:28
	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:18', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261' User entered 'None (0)'	System	29 Aug 2020 22:41:28
	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261' User entered 'No (N)'	System	29 Aug 2020 22:41:28
	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-29T18:41:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '10da9a6a-bedc-4673-b151-59b3f1519261' User entered '29 Aug 2020 18:41'	System	29 Aug 2020 22:41:28
	System	29 Aug 2020 22:41:28

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 5'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:36', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:03:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:04:07', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c' User entered 'None (0)'	System	31 Aug 2020 03:04:41
	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:04:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:04:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered 'No (N)'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-30T23:04:39', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b85fbaba-87cf-4905-9a1d-4b1747fbec6c'	System	31 Aug 2020 03:04:41
User entered '30 Aug 2020 23:04'	System	31 Aug 2020 03:04:41

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 6'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:50:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225' User entered 'None (0)'	System	31 Aug 2020 22:51:43
	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225'	System	31 Aug 2020 22:51:43
User entered 'Some interference with activity (2)'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225' User entered 'None (0)'	System	31 Aug 2020 22:51:43
	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:21', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225'	System	31 Aug 2020 22:51:43
User entered 'Some interference with activity (2)'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225' User entered 'None (0)'	System	31 Aug 2020 22:51:43
	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225'	System	31 Aug 2020 22:51:43
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:34', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225' User entered 'No (N)'	System	31 Aug 2020 22:51:43
	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-08-31T18:51:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cf2592bb-5ff6-42ba-8073-427020e13225' User entered '31 Aug 2020 18:51'	System	31 Aug 2020 22:51:43
	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 7'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T21:59:57', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'None (0)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'No interference with activity (1)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'None (0)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'No interference with activity (1)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf'	System	02 Sep 2020 02:00:55
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'None (0)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered 'No (N)'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-01T22:00:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '717f0d95-fefc-4660-a8c5-b22393b15baf' User entered '01 Sep 2020 22:00'	System	02 Sep 2020 02:00:55
	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	31 Aug 2020 22:51:43
User entered 'Day 8'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:56:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4c663404-cbc9-4ade-87a1-bc58d36bbf8b'	System	03 Sep 2020 01:56:41
User entered 'Some interference with activity (2)'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:56:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4c663404-cbc9-4ade-87a1-bc58d36bbf8b' User entered '02 Sep 2020 21:56'	System	03 Sep 2020 01:56:41
	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	02 Sep 2020 02:00:55
User entered 'Day 9'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:32:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '720a9c9f-4ab0-4ba7-852e-97bf89ada06f' User entered 'No interference with activity (1)'	System	04 Sep 2020 03:32:53
	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:32:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '720a9c9f-4ab0-4ba7-852e-97bf89ada06f' User entered '03 Sep 2020 23:32'	System	04 Sep 2020 03:32:53
	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	03 Sep 2020 01:56:41
User entered 'Day 10'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9303d72c-9f54-4f1b-a6e1-ee9e9ff8cfb3'	System	05 Sep 2020 04:22:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9303d72c-9f54-4f1b-a6e1-ee9e9ff8cfb3' User entered '05 Sep 2020 00:22'	System	05 Sep 2020 04:22:28
	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	04 Sep 2020 03:32:53
User entered 'Day 11'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:26', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7ed7e00a-a0be-40a2-92f6-18749bde809b'	System	06 Sep 2020 01:12:33
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7ed7e00a-a0be-40a2-92f6-18749bde809b' User entered '05 Sep 2020 21:12'	System	06 Sep 2020 01:12:33
	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	05 Sep 2020 04:22:28
User entered 'Day 12'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	06 Sep 2020 01:12:33
User entered 'Day 13'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '591b0ad2-0a78-43d7-8310-acf6ea32ec3b' User entered 'Some interference with activity (2)'	System	08 Sep 2020 04:25:44
	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '591b0ad2-0a78-43d7-8310-acf6ea32ec3b' User entered '08 Sep 2020 00:25'	System	08 Sep 2020 04:25:44
	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:44
User entered 'Day 14'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:53:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4fb0b855-2b60-40bd-8d43-721dc81a9648'	System	09 Sep 2020 01:53:47
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:53:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4fb0b855-2b60-40bd-8d43-721dc81a9648' User entered '08 Sep 2020 21:53'	System	09 Sep 2020 01:53:47
	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:44
User entered 'Day 15'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '684c8afb-91e2-48a3-924e-4d23721d9345'	System	09 Sep 2020 23:24:35
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '684c8afb-91e2-48a3-924e-4d23721d9345' User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:24:35
	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 01:53:47
User entered 'Day 16'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f1fd28c4-db83-476a-99cb-f8763fd47660'	System	11 Sep 2020 13:35:28
User entered 'No interference with activity (1)'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:26', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f1fd28c4-db83-476a-99cb-f8763fd47660'	System	11 Sep 2020 13:35:28
User entered '11 Sep 2020 09:35'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 23:24:35
User entered 'Day 17'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	11 Sep 2020 13:35:28
User entered 'Day 18'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b2b8829f-2a52-482a-8e19-d3df8285061c' User entered 'None (0)'	System	12 Sep 2020 17:28:08
	System	12 Sep 2020 17:28:08

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b2b8829f-2a52-482a-8e19-d3df8285061c' User entered '12 Sep 2020 13:28'	System	12 Sep 2020 17:28:08
	System	12 Sep 2020 17:28:08

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	31 Aug 2020 22:51:43
User entered 'Day 8'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:56:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8d124019-3330-4d53-8c6d-6160a8bbf77b'	System	03 Sep 2020 01:56:59
User entered 'No interference with activity (1)'	System	03 Sep 2020 01:56:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:56:56', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8d124019-3330-4d53-8c6d-6160a8bbf77b' User entered '02 Sep 2020 21:56'	System	03 Sep 2020 01:56:59
	System	03 Sep 2020 01:56:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	02 Sep 2020 02:00:55
User entered 'Day 9'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:32:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd3e43e88-fd9a-4eca-a247-fb4ac444e086'	System	04 Sep 2020 03:33:07
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:33:07

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:33:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd3e43e88-fd9a-4eca-a247-fb4ac444e086' User entered '03 Sep 2020 23:33'	System	04 Sep 2020 03:33:07
	System	04 Sep 2020 03:33:07

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	03 Sep 2020 01:56:59
User entered 'Day 10'	System	03 Sep 2020 01:56:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8f4789d8-3fbb-4638-a37a-e31ec4d0fb92'	System	05 Sep 2020 04:22:49
User entered 'No interference with activity (1)'	System	05 Sep 2020 04:22:49

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8f4789d8-3fbb-4638-a37a-e31ec4d0fb92'	System	05 Sep 2020 04:22:49
User entered '05 Sep 2020 00:22'	System	05 Sep 2020 04:22:49

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:56:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:56:59

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	04 Sep 2020 03:33:07
User entered 'Day 11'	System	04 Sep 2020 03:33:07

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '07059bfb-538d-4d17-b3e9-554518fdac84'	System	06 Sep 2020 01:12:39
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:12:39

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:36', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '07059bfb-538d-4d17-b3e9-554518fdac84' User entered '05 Sep 2020 21:12'	System	06 Sep 2020 01:12:39
	System	06 Sep 2020 01:12:39

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:07

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:07

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	05 Sep 2020 04:22:49
User entered 'Day 12'	System	05 Sep 2020 04:22:49

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 04:22:49

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 04:22:49

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	06 Sep 2020 01:12:39
User entered 'Day 13'	System	06 Sep 2020 01:12:39

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cc9c4f02-3a8a-4645-964d-1fb749672125'	System	08 Sep 2020 04:25:51
User entered 'No interference with activity (1)'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'cc9c4f02-3a8a-4645-964d-1fb749672125' User entered '08 Sep 2020 00:25'	System	08 Sep 2020 04:25:51
	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 01:12:39

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 01:12:39

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:51
User entered 'Day 14'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:53:55', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cf8e2d0-9a28-42f0-9a88-2e7e2214d144'	System	09 Sep 2020 01:54:00
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:54:00

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:53:58', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cf8e2d0-9a28-42f0-9a88-2e7e2214d144' User entered '08 Sep 2020 21:53'	System	09 Sep 2020 01:54:00
	System	09 Sep 2020 01:54:00

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:51
User entered 'Day 15'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ad5a9faa-3d64-400d-be77-4ed9bd00a332'	System	09 Sep 2020 23:24:44
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:24:44

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ad5a9faa-3d64-400d-be77-4ed9bd00a332' User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:24:44
	System	09 Sep 2020 23:24:44

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 04:25:51

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 01:54:00
User entered 'Day 16'	System	09 Sep 2020 01:54:00

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c94e901a-f9a1-472d-82eb-c8a86b7075f8'	System	11 Sep 2020 13:35:38
User entered 'No interference with activity (1)'	System	11 Sep 2020 13:35:38

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:34', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c94e901a-f9a1-472d-82eb-c8a86b7075f8' User entered '11 Sep 2020 09:35'	System	11 Sep 2020 13:35:38
	System	11 Sep 2020 13:35:38

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:54:00

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:54:00

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 23:24:44
User entered 'Day 17'	System	09 Sep 2020 23:24:44

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:24:44

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:24:44

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	11 Sep 2020 13:35:38
User entered 'Day 18'	System	11 Sep 2020 13:35:38

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b9303961-283a-4261-ab19-5987b65c7ad1'	System	12 Sep 2020 17:28:17
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b9303961-283a-4261-ab19-5987b65c7ad1' User entered '12 Sep 2020 13:28'	System	12 Sep 2020 17:28:17
	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:35:38

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:35:38

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	12 Sep 2020 17:28:17
User entered 'Day 19'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-13T17:32:21', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e6937b9-7101-4e1d-8d6d-c9419dd507ba'	System	13 Sep 2020 21:32:27
User entered 'No interference with activity (1)'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-13T17:32:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e6937b9-7101-4e1d-8d6d-c9419dd507ba' User entered '13 Sep 2020 17:32'	System	13 Sep 2020 21:32:27
	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	12 Sep 2020 17:28:17
User entered 'Day 20'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-14T13:24:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'de06e1ff-c5e3-4b1a-b949-efae81bfd581'	System	14 Sep 2020 17:25:06
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-14T13:25:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'de06e1ff-c5e3-4b1a-b949-efae81bfd581' User entered '14 Sep 2020 13:25'	System	14 Sep 2020 17:25:06
	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	13 Sep 2020 21:32:27
User entered 'Day 21'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-15T21:54:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1ebe628b-a1bd-4b09-9a62-26a7e490df7a' User entered 'Some interference with activity (2)'	System	16 Sep 2020 01:54:54
	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-15T21:54:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1ebe628b-a1bd-4b09-9a62-26a7e490df7a' User entered '15 Sep 2020 21:54'	System	16 Sep 2020 01:54:54
	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	14 Sep 2020 17:25:06
User entered 'Day 22'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-16T16:14:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a2e30975-8147-4b47-8e89-cbff1a57e6ec'	System	16 Sep 2020 20:14:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-16T16:14:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a2e30975-8147-4b47-8e89-cbff1a57e6ec' User entered '16 Sep 2020 16:14'	System	16 Sep 2020 20:14:37
	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	16 Sep 2020 01:54:54
User entered 'Day 23'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-17T23:59:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6cccf0e4-0fbe-4944-9ca8-a86b6e829e9b' User entered 'No interference with activity (1)'	System	18 Sep 2020 03:59:37
	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-17T23:59:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6cccf0e4-0fbe-4944-9ca8-a86b6e829e9b' User entered '17 Sep 2020 23:59'	System	18 Sep 2020 03:59:37
	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	16 Sep 2020 20:14:37
User entered 'Day 24'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	18 Sep 2020 03:59:37
User entered 'Day 25'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T00:12:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '43d64936-1da1-479b-9c4e-3d2578335a6a'	System	20 Sep 2020 04:12:26
User entered 'No interference with activity (1)'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T00:12:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '43d64936-1da1-479b-9c4e-3d2578335a6a' User entered '20 Sep 2020 00:12'	System	20 Sep 2020 04:12:26
	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 04:12:26
User entered 'Day 26'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T17:49:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0ab2a71e-97a4-4ead-9d43-4eadbc9efb04'	System	20 Sep 2020 21:49:53
User entered 'No interference with activity (1)'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T17:49:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0ab2a71e-97a4-4ead-9d43-4eadbc9efb04' User entered '20 Sep 2020 17:49'	System	20 Sep 2020 21:49:53
	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '20 Sep 2020 12:00'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '21 Sep 2020 11:59'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 04:12:26
User entered 'Day 27'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-22T00:28:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bdab8d7b-d0d3-487e-94d1-ea923435feaa' User entered 'No interference with activity (1)'	System	22 Sep 2020 04:28:42
	System	22 Sep 2020 04:28:42

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-22T00:28:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'bdab8d7b-d0d3-487e-94d1-ea923435feaa' User entered '22 Sep 2020 00:28'	System	22 Sep 2020 04:28:42
	System	22 Sep 2020 04:28:42

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 21:49:53
User entered 'Day 28'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T02:17:03', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '82f4967f-a512-4479-b34e-10b04d7fbe22' User entered 'None (0)'	System	23 Sep 2020 06:17:09
	System	23 Sep 2020 06:17:09

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T02:17:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '82f4967f-a512-4479-b34e-10b04d7fbe22' User entered '23 Sep 2020 02:17'	System	23 Sep 2020 06:17:09
	System	23 Sep 2020 06:17:09

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	02 Sep 2020 02:00:55
User entered 'Day 8'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:57:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '69563f7d-dba4-4cd3-b769-43369d313619'	System	03 Sep 2020 01:57:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 01:57:15

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:57:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '69563f7d-dba4-4cd3-b769-43369d313619' User entered '02 Sep 2020 21:57'	System	03 Sep 2020 01:57:15
	System	03 Sep 2020 01:57:15

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	02 Sep 2020 02:00:55
User entered 'Day 9'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:33:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd62af4c3-d01c-4ebf-9827-bfe7f3205ec6' User entered 'None (0)'	System	04 Sep 2020 03:33:11
	System	04 Sep 2020 03:33:11

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:33:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd62af4c3-d01c-4ebf-9827-bfe7f3205ec6' User entered '03 Sep 2020 23:33'	System	04 Sep 2020 03:33:11
	System	04 Sep 2020 03:33:11

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	31 Aug 2020 22:51:43
User entered 'Day 8'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:57:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f122501b-c13a-4b4e-afe5-b3d23d636dd4' User entered 'No (N)'	System	03 Sep 2020 01:57:33
	System	03 Sep 2020 01:57:33

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-02T21:57:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f122501b-c13a-4b4e-afe5-b3d23d636dd4' User entered '02 Sep 2020 21:57'	System	03 Sep 2020 01:57:33
	System	03 Sep 2020 01:57:33

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 22:51:43

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	02 Sep 2020 02:00:55
User entered 'Day 9'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:33:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '81569dc5-0ec6-466f-95ab-a7a4152ebf15' User entered 'No (N)'	System	04 Sep 2020 03:33:23
	System	04 Sep 2020 03:33:23

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-03T23:33:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '81569dc5-0ec6-466f-95ab-a7a4152ebf15' User entered '03 Sep 2020 23:33'	System	04 Sep 2020 03:33:23
	System	04 Sep 2020 03:33:23

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:00:55

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	03 Sep 2020 01:56:41
User entered 'Day 10'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9bdaf0f8-c2bf-4ba7-bab7-174fe9663557' User entered 'No (N)'	System	05 Sep 2020 04:22:54
	System	05 Sep 2020 04:22:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T00:22:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9bdaf0f8-c2bf-4ba7-bab7-174fe9663557' User entered '05 Sep 2020 00:22'	System	05 Sep 2020 04:22:54
	System	05 Sep 2020 04:22:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:56:41

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	04 Sep 2020 03:32:53
User entered 'Day 11'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3e3ffeaf-ca50-4426-b752-f840152ea595'	System	06 Sep 2020 01:12:50
User entered 'No (N)'	System	06 Sep 2020 01:12:50

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-05T21:12:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3e3ffeaf-ca50-4426-b752-f840152ea595' User entered '05 Sep 2020 21:12'	System	06 Sep 2020 01:12:50
	System	06 Sep 2020 01:12:50

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:32:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	05 Sep 2020 04:22:28
User entered 'Day 12'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 04:22:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	06 Sep 2020 01:12:33
User entered 'Day 13'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '90d60a7b-943c-48e6-a139-9f671c5d1ebc' User entered 'No (N)'	System	08 Sep 2020 04:25:54
	System	08 Sep 2020 04:25:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T00:25:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '90d60a7b-943c-48e6-a139-9f671c5d1ebc' User entered '08 Sep 2020 00:25'	System	08 Sep 2020 04:25:54
	System	08 Sep 2020 04:25:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 01:12:33

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:44
User entered 'Day 14'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:54:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '88eb97a0-643d-4be7-816a-0ffbb8ed9685' User entered 'No (N)'	System	09 Sep 2020 01:54:09
	System	09 Sep 2020 01:54:09

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-08T21:54:07', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '88eb97a0-643d-4be7-816a-0ffbb8ed9685' User entered '08 Sep 2020 21:54'	System	09 Sep 2020 01:54:09
	System	09 Sep 2020 01:54:09

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	08 Sep 2020 04:25:44
User entered 'Day 15'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '890352d8-9a55-48a9-8923-b6fec065621' User entered 'No (N)'	System	09 Sep 2020 23:24:53
	System	09 Sep 2020 23:24:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-09T19:24:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '890352d8-9a55-48a9-8923-b6fec065621' User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:24:53
	System	09 Sep 2020 23:24:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 04:25:44

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 01:53:47
User entered 'Day 16'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0fbceb82-1459-43a4-afc0-371bd83c5357' User entered 'No (N)'	System	11 Sep 2020 13:35:50
	System	11 Sep 2020 13:35:50

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-11T09:35:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0fbee82-1459-43a4-afc0-371bd83c5357' User entered '11 Sep 2020 09:35'	System	11 Sep 2020 13:35:50
	System	11 Sep 2020 13:35:50

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:53:47

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	09 Sep 2020 23:24:35
User entered 'Day 17'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:24:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	11 Sep 2020 13:35:28
User entered 'Day 18'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1814b9d5-b630-4395-8400-49a5b3648f85'	System	12 Sep 2020 17:28:25
User entered 'No (N)'	System	12 Sep 2020 17:28:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-12T13:28:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1814b9d5-b630-4395-8400-49a5b3648f85' User entered '12 Sep 2020 13:28'	System	12 Sep 2020 17:28:25
	System	12 Sep 2020 17:28:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:35:28

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	12 Sep 2020 17:28:17
User entered 'Day 19'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-13T17:32:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a37ae9ed-3926-4f3a-8d2f-843ff39f8d67'	System	13 Sep 2020 21:32:35
User entered 'No (N)'	System	13 Sep 2020 21:32:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-13T17:32:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a37ae9ed-3926-4f3a-8d2f-843ff39f8d67' User entered '13 Sep 2020 17:32'	System	13 Sep 2020 21:32:35
	System	13 Sep 2020 21:32:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	12 Sep 2020 17:28:17
User entered 'Day 20'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-14T13:25:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c40fbb6c-4ae9-4f28-b9b9-ec0be9602cb6'	System	14 Sep 2020 17:25:14
User entered 'No (N)'	System	14 Sep 2020 17:25:14

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-14T13:25:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c40fbb6c-4ae9-4f28-b9b9-ec0be9602cb6' User entered '14 Sep 2020 13:25'	System	14 Sep 2020 17:25:14
	System	14 Sep 2020 17:25:14

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:28:17

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	13 Sep 2020 21:32:27
User entered 'Day 21'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-15T21:54:54', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b3632c-6f18-46e4-aeb0-4da1ee7095fb' User entered 'No (N)'	System	16 Sep 2020 01:55:00
	System	16 Sep 2020 01:55:00

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-15T21:54:57', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '62b3632c-6f18-46e4-aeb0-4da1ee7095fb' User entered '15 Sep 2020 21:54'	System	16 Sep 2020 01:55:00
	System	16 Sep 2020 01:55:00

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 21:32:27

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	14 Sep 2020 17:25:06
User entered 'Day 22'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-16T16:14:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1c8a49ec-da67-4c47-a67e-c93573d0b89f' User entered 'No (N)'	System	16 Sep 2020 20:14:45
	System	16 Sep 2020 20:14:45

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-16T16:14:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1c8a49ec-da67-4c47-a67e-c93573d0b89f' User entered '16 Sep 2020 16:14'	System	16 Sep 2020 20:14:45
	System	16 Sep 2020 20:14:45

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:25:06

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	16 Sep 2020 01:54:54
User entered 'Day 23'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-17T23:59:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '306b495a-2ec6-453c-9a0d-4db2600d74f2'	System	18 Sep 2020 03:59:42
User entered 'No (N)'	System	18 Sep 2020 03:59:42

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-17T23:59:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '306b495a-2ec6-453c-9a0d-4db2600d74f2' User entered '17 Sep 2020 23:59'	System	18 Sep 2020 03:59:42
	System	18 Sep 2020 03:59:42

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:54:54

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	16 Sep 2020 20:14:37
User entered 'Day 24'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:14:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	18 Sep 2020 03:59:37
User entered 'Day 25'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T00:12:28', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9af87122-d14b-465a-aaff-29cab9715f4f'	System	20 Sep 2020 04:12:35
User entered 'No (N)'	System	20 Sep 2020 04:12:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T00:12:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '9af87122-d14b-465a-aaff-29cab9715f4f' User entered '20 Sep 2020 00:12'	System	20 Sep 2020 04:12:35
	System	20 Sep 2020 04:12:35

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:59:37

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 04:12:26
User entered 'Day 26'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T17:49:57', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '39f4bf68-9994-4069-8358-b393d6d7f703'	System	20 Sep 2020 21:50:25
User entered 'No (N)'	System	20 Sep 2020 21:50:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-20T17:50:22', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '39f4bf68-9994-4069-8358-b393d6d7f703' User entered '20 Sep 2020 17:50'	System	20 Sep 2020 21:50:25
	System	20 Sep 2020 21:50:25

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '20 Sep 2020 12:00'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '21 Sep 2020 11:59'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 04:12:26
User entered 'Day 27'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-22T00:28:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '28cdcdc4-fb56-494c-a2ed-f36960b28b4d' User entered 'No (N)'	System	22 Sep 2020 04:28:49
	System	22 Sep 2020 04:28:49

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-22T00:28:48', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '28cdcdc4-fb56-494c-a2ed-f36960b28b4d' User entered '22 Sep 2020 00:28'	System	22 Sep 2020 04:28:49
	System	22 Sep 2020 04:28:49

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 04:12:26

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	20 Sep 2020 21:49:53
User entered 'Day 28'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T02:17:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '96fc399a-a235-4d12-8387-e4ad7583a259'	System	23 Sep 2020 06:17:15
User entered 'No (N)'	System	23 Sep 2020 06:17:15

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T02:17:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '96fc399a-a235-4d12-8387-e4ad7583a259' User entered '23 Sep 2020 02:17'	System	23 Sep 2020 06:17:15
	System	23 Sep 2020 06:17:15

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 21:49:53

US3542061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 21:49:53

US3542061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:46

US3542061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:46

US3542061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:46

US3542061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:46

US3542061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:49

US3542061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	10 Sep 2020 19:05:49

US3542061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:59

US3542061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:20:35
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:20:35
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 04:53:18
User entered '9 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 19:05:59

US3542061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:59

US3542061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:05:59

US3542061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 04:53:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:06:02

US3542061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	10 Sep 2020 19:06:02

US3542061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:18:53
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:08:29

US3542061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:18:53
User entered '16 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:08:29

US3542061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:18:53
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:08:29

US3542061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:18:53
User entered empty.	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:08:29

US3542061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:18:53
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:08:34

US3542061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	17 Sep 2020 15:08:34

US3542061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:16:33

US3542061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:16:33

US3542061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:16:33

US3542061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'VISIT2'	System	23 Sep 2020 16:16:33

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '07:40'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '23 Sep 2020 07:40'	System	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:11:05
User entered '98.2' F	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:11:05
User entered '72'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'bpm'	System	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:11:05
User entered '16'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'breaths/min'	System	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:11:05
User entered '130'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:11:05
User entered '79'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	23 Sep 2020 16:17:15

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:18:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:18:13
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '09:01'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '23 Sep 2020 09:01'	System	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:18:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:18:13
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '64'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'bpm'	System	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'breaths/min'	System	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '115'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered '73'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	24 Sep 2020 18:46:03

US3542061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:16:43

US3542061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:16:43

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:18:53
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4)	23 Sep 2020 12:32:05
	(b) (4)	

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:18:53
User entered empty.	(b) (4) Hira Qadir (b) (4)	23 Sep 2020 12:32:05
	(b) (4)	

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:18:53
User entered empty.	(b) (4) Hira Qadir (b) (4)	23 Sep 2020 12:32:05
	(b) (4)	

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:18:53
User entered '23 Sep 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:18:53
User entered '08:24'	(b) (4) Hira Qadir (b) (4)	23 Sep 2020 12:32:05
	(b) (4)	

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '23 Sep 2020 08:24'	System	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:18:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hira Qadir (b) (4) (b) (4)	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'ONCE'	System	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 12:32:05

US3542061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:17:28

US3542061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:17:28

US3542061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '07:55' reason for change: Data Entry Error	(b) (4)	
	Taylor Ladson (b) (4)	23 Sep 2020 16:18:23
User entered '07:56'	(b) (4)	
	Taylor Ladson (b) (4)	23 Sep 2020 16:17:28
	(b) (4)	

US3542061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '23 Sep 2020 07:55'	System	23 Sep 2020 16:18:23
User entered '23 Sep 2020 07:56'	System	23 Sep 2020 16:17:28

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '07:56'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '23 Sep 2020 07:56'	System	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered empty.	System	23 Sep 2020 16:18:16

US3542061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:46:36

US3542061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'I'	System	24 Sep 2020 18:46:36

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:04:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e0fb42cd-01dd-4e08-a3df-438c9654c25c' User entered 'Yes (Y)'	System	23 Sep 2020 13:04:53
	System	23 Sep 2020 13:04:53

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:04:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e0fb42cd-01dd-4e08-a3df-438c9654c25c' User entered '97.9'	System	23 Sep 2020 13:04:53
	System	23 Sep 2020 13:04:53

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:04:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e0fb42cd-01dd-4e08-a3df-438c9654c25c'	System	23 Sep 2020 13:04:53
User entered 'No (N)'	System	23 Sep 2020 13:04:53

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:04:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e0fb42cd-01dd-4e08-a3df-438c9654c25c' User entered '23 Sep 2020 09:04'	System	23 Sep 2020 13:04:53
	System	23 Sep 2020 13:04:53

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 08:44'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 11:14'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:00:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '58d786ef-93c8-492b-88ee-41c871b14d16' User entered 'Yes (Y)'	System	24 Sep 2020 04:00:57
	System	24 Sep 2020 04:00:57

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:00:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '58d786ef-93c8-492b-88ee-41c871b14d16' User entered '97.6'	System	24 Sep 2020 04:00:57
	System	24 Sep 2020 04:00:57

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:00:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '58d786ef-93c8-492b-88ee-41c871b14d16' User entered 'No (N)'	System	24 Sep 2020 04:00:57
	System	24 Sep 2020 04:00:57

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:00:53', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '58d786ef-93c8-492b-88ee-41c871b14d16' User entered '24 Sep 2020 00:00'	System	24 Sep 2020 04:00:57
	System	24 Sep 2020 04:00:57

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 12:09'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 2'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:38:57', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a859ca20-7b1c-4df0-bdc1-b943e7c4cb96' User entered 'Yes (Y)'	System	25 Sep 2020 02:39:16
	System	25 Sep 2020 02:39:16

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a859ca20-7b1c-4df0-bdc1-b943e7c4cb96' User entered '97.8'	System	25 Sep 2020 02:39:16
	System	25 Sep 2020 02:39:16

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a859ca20-7b1c-4df0-bdc1-b943e7c4cb96'	System	25 Sep 2020 02:39:16
User entered 'No (N)'	System	25 Sep 2020 02:39:16

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a859ca20-7b1c-4df0-bdc1-b943e7c4cb96'	System	25 Sep 2020 02:39:16
User entered '24 Sep 2020 22:39'	System	25 Sep 2020 02:39:16

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 3'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:29:36', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '86ef007d-e58e-45e4-a8fa-ac0baf1a0240' User entered 'Yes (Y)'	System	26 Sep 2020 04:29:56
	System	26 Sep 2020 04:29:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:29:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '86ef007d-e58e-45e4-a8fa-ac0baf1a0240' User entered '97.8'	System	26 Sep 2020 04:29:56
	System	26 Sep 2020 04:29:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:29:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '86ef007d-e58e-45e4-a8fa-ac0baf1a0240'	System	26 Sep 2020 04:29:56
User entered 'No (N)'	System	26 Sep 2020 04:29:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:29:54', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '86ef007d-e58e-45e4-a8fa-ac0baf1a0240' User entered '26 Sep 2020 00:29'	System	26 Sep 2020 04:29:56
	System	26 Sep 2020 04:29:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 4'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:07:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8347034b-a6b6-4889-8957-flb3ed15cd84' User entered 'Yes (Y)'	System	27 Sep 2020 04:07:56
	System	27 Sep 2020 04:07:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:07:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8347034b-a6b6-4889-8957-flb3ed15cd84' User entered '97.9'	System	27 Sep 2020 04:07:56
	System	27 Sep 2020 04:07:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:07:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8347034b-a6b6-4889-8957-flb3ed15cd84' User entered 'No (N)'	System	27 Sep 2020 04:07:56
	System	27 Sep 2020 04:07:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:07:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8347034b-a6b6-4889-8957-flb3ed15cd84' User entered '27 Sep 2020 00:07'	System	27 Sep 2020 04:07:56
	System	27 Sep 2020 04:07:56

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 5'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4320ab02-7af9-40f6-9af1-fa15e36ed235'	System	27 Sep 2020 20:12:24
User entered 'Yes (Y)'	System	27 Sep 2020 20:12:24

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:13', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4320ab02-7af9-40f6-9af1-fa15e36ed235' User entered '97.8'	System	27 Sep 2020 20:12:24
	System	27 Sep 2020 20:12:24

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4320ab02-7af9-40f6-9af1-fa15e36ed235'	System	27 Sep 2020 20:12:24
User entered 'No (N)'	System	27 Sep 2020 20:12:24

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4320ab02-7af9-40f6-9af1-fa15e36ed235'	System	27 Sep 2020 20:12:24
User entered '27 Sep 2020 16:12'	System	27 Sep 2020 20:12:24

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 6'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '61e2a1ef-e571-4630-afdd-9df0e071061f' User entered 'Yes (Y)'	System	29 Sep 2020 04:03:29
	System	29 Sep 2020 04:03:29

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '61e2a1ef-e571-4630-afdd-9df0e071061f' User entered '97.6'	System	29 Sep 2020 04:03:29
	System	29 Sep 2020 04:03:29

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '61e2a1ef-e571-4630-afdd-9df0e071061f' User entered 'No (N)'	System	29 Sep 2020 04:03:29
	System	29 Sep 2020 04:03:29

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:26', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '61e2a1ef-e571-4630-afdd-9df0e071061f' User entered '29 Sep 2020 00:03'	System	29 Sep 2020 04:03:29
	System	29 Sep 2020 04:03:29

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 7'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:04:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b743d58f-a9bd-482e-bef1-e234c90f92dd'	System	23 Sep 2020 13:05:20
User entered 'None (1)'	System	23 Sep 2020 13:05:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b743d58f-a9bd-482e-bef1-e234c90f92dd' User entered 'No (N)'	System	23 Sep 2020 13:05:20
	System	23 Sep 2020 13:05:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:07', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b743d58f-a9bd-482e-bef1-e234c90f92dd' User entered 'No (N)'	System	23 Sep 2020 13:05:20
	System	23 Sep 2020 13:05:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b743d58f-a9bd-482e-bef1-e234c90f92dd'	System	23 Sep 2020 13:05:20
User entered 'None (1)'	System	23 Sep 2020 13:05:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b743d58f-a9bd-482e-bef1-e234c90f92dd' User entered '23 Sep 2020 09:05'	System	23 Sep 2020 13:05:20
	System	23 Sep 2020 13:05:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 08:44'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 11:14'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e6377d95-5ec5-4928-b8ec-2be75bff298f' User entered 'None (1)'	System	24 Sep 2020 04:01:20
	System	24 Sep 2020 04:01:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:03', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e6377d95-5ec5-4928-b8ec-2be75bff298f' User entered 'No (N)'	System	24 Sep 2020 04:01:20
	System	24 Sep 2020 04:01:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e6377d95-5ec5-4928-b8ec-2be75bff298f' User entered 'No (N)'	System	24 Sep 2020 04:01:20
	System	24 Sep 2020 04:01:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e6377d95-5ec5-4928-b8ec-2be75bff298f' User entered 'None (1)'	System	24 Sep 2020 04:01:20
	System	24 Sep 2020 04:01:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:18', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'e6377d95-5ec5-4928-b8ec-2be75bff298f' User entered '24 Sep 2020 00:01'	System	24 Sep 2020 04:01:20
	System	24 Sep 2020 04:01:20

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 12:09'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 2'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:21', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8c0e3ee6-037d-42a6-aa8e-5f7dffedb77a'	System	25 Sep 2020 02:40:05
User entered 'None (1)'	System	25 Sep 2020 02:40:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8c0e3ee6-037d-42a6-aa8e-5f7dffedb77a' User entered 'No (N)'	System	25 Sep 2020 02:40:05
	System	25 Sep 2020 02:40:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8c0e3ee6-037d-42a6-aa8e-5f7dffedb77a'	System	25 Sep 2020 02:40:05
User entered 'No (N)'	System	25 Sep 2020 02:40:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:39:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8c0e3ee6-037d-42a6-aa8e-5f7dffedb77a'	System	25 Sep 2020 02:40:05
User entered 'None (1)'	System	25 Sep 2020 02:40:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:01', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8c0e3ee6-037d-42a6-aa8e-5f7dffedb77a'	System	25 Sep 2020 02:40:05
User entered '24 Sep 2020 22:40'	System	25 Sep 2020 02:40:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 3'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:29:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '529b261b-27c6-47e5-92aa-b83920b88dcb' User entered 'None (1)'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '529b261b-27c6-47e5-92aa-b83920b88dcb' User entered 'No (N)'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '529b261b-27c6-47e5-92aa-b83920b88dcb' User entered 'No (N)'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '529b261b-27c6-47e5-92aa-b83920b88dcb' User entered 'None (1)'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '529b261b-27c6-47e5-92aa-b83920b88dcb' User entered '26 Sep 2020 00:30'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 4'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:07:58', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fa897366-2797-4b0e-84d4-a432cf0fbc61'	System	27 Sep 2020 04:08:13
User entered 'None (1)'	System	27 Sep 2020 04:08:13

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fa897366-2797-4b0e-84d4-a432cf0fbc61' User entered 'No (N)'	System	27 Sep 2020 04:08:13
	System	27 Sep 2020 04:08:13

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:03', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fa897366-2797-4b0e-84d4-a432cf0fbc61' User entered 'No (N)'	System	27 Sep 2020 04:08:13
	System	27 Sep 2020 04:08:13

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:07', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fa897366-2797-4b0e-84d4-a432cf0fbc61'	System	27 Sep 2020 04:08:13
User entered 'None (1)'	System	27 Sep 2020 04:08:13

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'fa897366-2797-4b0e-84d4-a432cf0fbc61' User entered '27 Sep 2020 00:08'	System	27 Sep 2020 04:08:13
	System	27 Sep 2020 04:08:13

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 5'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '670d29c7-73bd-4dec-a4dc-7a62ef40c195'	System	27 Sep 2020 20:12:40
User entered 'None (1)'	System	27 Sep 2020 20:12:40

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '670d29c7-73bd-4dec-a4dc-7a62ef40c195' User entered 'No (N)'	System	27 Sep 2020 20:12:40
	System	27 Sep 2020 20:12:40

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '670d29c7-73bd-4dec-a4dc-7a62ef40c195'	System	27 Sep 2020 20:12:40
User entered 'No (N)'	System	27 Sep 2020 20:12:40

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:34', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '670d29c7-73bd-4dec-a4dc-7a62ef40c195'	System	27 Sep 2020 20:12:40
User entered 'None (1)'	System	27 Sep 2020 20:12:40

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:36', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '670d29c7-73bd-4dec-a4dc-7a62ef40c195' User entered '27 Sep 2020 16:12'	System	27 Sep 2020 20:12:40
	System	27 Sep 2020 20:12:40

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 6'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:32', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '54fba78f-0f7b-4179-a21a-c2bd6b6c77cc'	System	29 Sep 2020 04:03:48
User entered 'None (1)'	System	29 Sep 2020 04:03:48

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '54fba78f-0f7b-4179-a21a-c2bd6b6c77cc' User entered 'No (N)'	System	29 Sep 2020 04:03:48
	System	29 Sep 2020 04:03:48

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '54fba78f-0f7b-4179-a21a-c2bd6b6c77cc' User entered 'No (N)'	System	29 Sep 2020 04:03:48
	System	29 Sep 2020 04:03:48

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '54fba78f-0f7b-4179-a21a-c2bd6b6c77cc'	System	29 Sep 2020 04:03:48
User entered 'None (1)'	System	29 Sep 2020 04:03:48

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '54fba78f-0f7b-4179-a21a-c2bd6b6c77cc' User entered '29 Sep 2020 00:03'	System	29 Sep 2020 04:03:48
	System	29 Sep 2020 04:03:48

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 7'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:34', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'None (0)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered 'No (N)'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-23T09:05:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7594545c-b78a-46f6-ab9b-909ab99cad3b' User entered '23 Sep 2020 09:05'	System	23 Sep 2020 13:05:53
	System	23 Sep 2020 13:05:53

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 08:44'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 11:14'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered 'None (0)'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1'	System	24 Sep 2020 04:02:09
User entered 'No interference with activity (1)'	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered 'None (0)'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:49', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1'	System	24 Sep 2020 04:02:09
User entered 'No interference with activity (1)'	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:53', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered 'None (0)'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:01:56', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered 'None (0)'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:02:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered 'No (N)'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T00:02:06', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '17b441f1-be46-4123-9746-05217915aad1' User entered '24 Sep 2020 00:02'	System	24 Sep 2020 04:02:09
	System	24 Sep 2020 04:02:09

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '23 Sep 2020 12:09'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 2'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:08', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'None (0)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518'	System	25 Sep 2020 02:40:31
User entered 'No interference with activity (1)'	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'None (0)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'None (0)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'None (0)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'None (0)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered 'No (N)'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-24T22:40:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24bed338-f24c-4b81-b4c1-e4bb88fbb518' User entered '24 Sep 2020 22:40'	System	25 Sep 2020 02:40:31
	System	25 Sep 2020 02:40:31

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 3'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered 'None (0)'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:28', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110'	System	26 Sep 2020 04:30:57
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered 'None (0)'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110'	System	26 Sep 2020 04:30:57
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered 'None (0)'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered 'None (0)'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered 'No (N)'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-26T00:30:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1cea7883-c1ed-4874-8db2-15f0c1396110' User entered '26 Sep 2020 00:30'	System	26 Sep 2020 04:30:57
	System	26 Sep 2020 04:30:57

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 4'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:14', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered 'None (0)'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56'	System	27 Sep 2020 04:08:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered 'None (0)'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered 'None (0)'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:36', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered 'None (0)'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered 'None (0)'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56'	System	27 Sep 2020 04:08:49
User entered 'No (N)'	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T00:08:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '7e426117-63ae-413a-be20-e6f399501c56' User entered '27 Sep 2020 00:08'	System	27 Sep 2020 04:08:49
	System	27 Sep 2020 04:08:49

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 5'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered 'None (0)'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:12:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e'	System	27 Sep 2020 20:13:42
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered 'None (0)'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered 'No interference with activity (1)'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:08', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered 'None (0)'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e'	System	27 Sep 2020 20:13:42
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:23', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered 'No (N)'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-27T16:13:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '359fabb4-6d41-4a57-9f54-aa80fbf3d60e' User entered '27 Sep 2020 16:13'	System	27 Sep 2020 20:13:42
	System	27 Sep 2020 20:13:42

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 6'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:03:51', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb' User entered 'None (0)'	System	29 Sep 2020 04:04:29
	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb'	System	29 Sep 2020 04:04:29
User entered 'No interference with activity (1)'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:08', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb' User entered 'None (0)'	System	29 Sep 2020 04:04:29
	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:11', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb'	System	29 Sep 2020 04:04:29
User entered 'No interference with activity (1)'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:17', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb'	System	29 Sep 2020 04:04:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:21', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb'	System	29 Sep 2020 04:04:29
User entered 'No interference with activity (1)'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:24', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb'	System	29 Sep 2020 04:04:29
User entered 'No (N)'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-09-29T00:04:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8ebff93f-bbf5-43da-8fbe-2eabd409f0cb' User entered '29 Sep 2020 00:04'	System	29 Sep 2020 04:04:29
	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	23 Sep 2020 12:32:05
User entered 'Day 7'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:32:05

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	29 Sep 2020 04:04:29
User entered 'Day 8'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:39:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd6f251f1-e107-4e7d-b421-08ce233bdf10'	System	01 Oct 2020 07:39:52
User entered 'No interference with activity (1)'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:39:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd6f251f1-e107-4e7d-b421-08ce233bdf10' User entered '01 Oct 2020 03:39'	System	01 Oct 2020 07:39:52
	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	01 Oct 2020 07:39:52
User entered 'Day 9'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T20:34:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '09a4c79b-d6f4-4c8e-8841-6a798621d228'	System	02 Oct 2020 00:35:07
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:35:07

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T20:35:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '09a4c79b-d6f4-4c8e-8841-6a798621d228' User entered '01 Oct 2020 20:35'	System	02 Oct 2020 00:35:07
	System	02 Oct 2020 00:35:07

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	01 Oct 2020 07:39:52
User entered 'Day 10'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-02T23:22:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '319f45b4-b2bb-4107-bd1a-088e4c852b57' User entered 'None (0)'	System	03 Oct 2020 03:22:48
	System	03 Oct 2020 03:22:48

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-02T23:22:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '319f45b4-b2bb-4107-bd1a-088e4c852b57' User entered '02 Oct 2020 23:22'	System	03 Oct 2020 03:22:48
	System	03 Oct 2020 03:22:48

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	29 Sep 2020 04:04:29
User entered 'Day 8'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c2c0280a-8579-4ce0-adb2-bccde4c9a465' User entered 'None (0)'	System	01 Oct 2020 07:40:11
	System	01 Oct 2020 07:40:11

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c2c0280a-8579-4ce0-adb2-bccde4c9a465' User entered '01 Oct 2020 03:40'	System	01 Oct 2020 07:40:11
	System	01 Oct 2020 07:40:11

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	29 Sep 2020 04:04:29
User entered 'Day 8'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:16', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0c1f7a98-2dff-45c5-bd3b-71c720326f57' User entered 'None (0)'	System	01 Oct 2020 07:40:22
	System	01 Oct 2020 07:40:22

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '0c1f7a98-2dff-45c5-bd3b-71c720326f57' User entered '01 Oct 2020 03:40'	System	01 Oct 2020 07:40:22
	System	01 Oct 2020 07:40:22

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	29 Sep 2020 04:04:29
User entered 'Day 8'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ee0cffd0-5420-4c03-8233-69e9d551f5cc' User entered 'None (0)'	System	01 Oct 2020 07:40:35
	System	01 Oct 2020 07:40:35

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ee0cffd0-5420-4c03-8233-69e9d551f5cc' User entered '01 Oct 2020 03:40'	System	01 Oct 2020 07:40:35
	System	01 Oct 2020 07:40:35

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	29 Sep 2020 04:04:29
User entered 'Day 8'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:34', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a8babaa6-14a0-405d-921d-c797bbb6ce23' User entered 'No (N)'	System	01 Oct 2020 07:40:39
	System	01 Oct 2020 07:40:39

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-01T03:40:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a8babaa6-14a0-405d-921d-c797bbb6ce23' User entered '01 Oct 2020 03:40'	System	01 Oct 2020 07:40:39
	System	01 Oct 2020 07:40:39

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 04:04:29

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	01 Oct 2020 07:39:52
User entered 'Day 10'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-02T23:22:47', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f9606385-fc30-4293-9984-fc2b004fa8f5' User entered 'No (N)'	System	03 Oct 2020 03:22:55
	System	03 Oct 2020 03:22:55

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-02T23:22:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f9606385-fc30-4293-9984-fc2b004fa8f5' User entered '02 Oct 2020 23:22'	System	03 Oct 2020 03:22:55
	System	03 Oct 2020 03:22:55

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 07:39:52

US3542061

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:04:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 07:39:52

US3542061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:29:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:14:21

US3542061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:12:12
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:12:12
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	03 Oct 2020 15:29:10
User entered '1 Oct 2020'	(b) (4)	
	Erika Faust (b) (4)	02 Oct 2020 20:14:21
	(b) (4)	

US3542061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:29:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:14:21

US3542061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:29:10
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:14:21

US3542061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:29:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:14:25

US3542061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'I'	System	02 Oct 2020 20:14:25

US3542061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 02:23:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:18:29

US3542061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:11:42
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:11:42
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Oct 2020 02:23:45
User entered '8 Oct 2020'	(b) (4)	
	Erika Faust (b) (4)	09 Oct 2020 17:18:29
	(b) (4)	

US3542061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:23:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:18:29

US3542061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 02:23:45
User entered empty.	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:18:29

US3542061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 02:23:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:18:33

US3542061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	09 Oct 2020 17:18:33

US3542061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	19 Oct 2020 16:44:31

US3542061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '16 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	19 Oct 2020 16:44:31

US3542061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	19 Oct 2020 16:44:31

US3542061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:33:32
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	19 Oct 2020 16:44:31
	(b) (4)	

US3542061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	19 Oct 2020 16:44:36

US3542061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	19 Oct 2020 16:44:36

US3542061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:21

US3542061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '20 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:21

US3542061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered 'Clinic (Clinic)'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:21

US3542061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'VISIT3'	System	21 Oct 2020 15:56:21

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '20 Oct 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '10:30'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '20 Oct 2020 10:30'	System	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered '98.3' F	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered '64'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'bpm'	System	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered '16'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'breaths/min'	System	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered '142'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:33:32
User entered '80'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'mmHg'	System	21 Oct 2020 15:56:54

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28

US3542061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28

US3542061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:56:25

US3542061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:56:25

US3542061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:57:05

US3542061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '20 Oct 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:57:05

US3542061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered '10:40'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 15:57:05

US3542061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered '20 Oct 2020 10:40'	System	21 Oct 2020 15:57:05

US3542061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 15:55:59

US3542061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'I'	System	21 Oct 2020 15:55:59

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 64'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-26T23:59:30', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '855c125d-1e1d-4de8-920a-9a227a96f204'	System	27 Oct 2020 03:59:45
User entered 'No (N)'	System	27 Oct 2020 03:59:45

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-26T23:59:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '855c125d-1e1d-4de8-920a-9a227a96f204'	System	27 Oct 2020 03:59:45
User entered 'No (N)'	System	27 Oct 2020 03:59:45

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-10-26T23:59:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '855c125d-1e1d-4de8-920a-9a227a96f204' User entered '26 Oct 2020 23:59:42'	System	27 Oct 2020 03:59:45
	System	27 Oct 2020 03:59:45

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 71'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-02T15:24:04', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3453f864-6396-45cf-81cd-201100d0136a' User entered 'No (N)'	System	02 Nov 2020 20:28:09
	System	02 Nov 2020 20:28:09

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-02T15:22:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3453f864-6396-45cf-81cd-201100d0136a' User entered 'No (N)'	System	02 Nov 2020 20:28:09
	System	02 Nov 2020 20:28:09

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-02T15:28:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3453f864-6396-45cf-81cd-201100d0136a' User entered '02 Nov 2020 15:28:05'	System	02 Nov 2020 20:28:09
	System	02 Nov 2020 20:28:09

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered 'Day 78'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-09T00:01:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b31d6afa-52b0-4f24-b728-66a8c3c3942f' User entered 'No (N)'	System	09 Nov 2020 05:02:19
	System	09 Nov 2020 05:02:19

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-09T00:02:09', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b31d6afa-52b0-4f24-b728-66a8c3c3942f' User entered 'No (N)'	System	09 Nov 2020 05:02:19
	System	09 Nov 2020 05:02:19

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-09T00:02:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b31d6afa-52b0-4f24-b728-66a8c3c3942f' User entered '09 Nov 2020 00:02:15'	System	09 Nov 2020 05:02:19
	System	09 Nov 2020 05:02:19

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 14:35:04

US3542061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:38:25
Data entry locked.	System	26 Aug 2020 14:35:04
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 14:35:04

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-20T00:55:27', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a26e4120-f78e-484a-b6c8-267ca6b1816b' User entered 'No (N)'	System	20 Nov 2020 05:55:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-20T00:55:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a26e4120-f78e-484a-b6c8-267ca6b1816b' User entered 'No (N)'	System	20 Nov 2020 05:55:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-20T00:55:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'a26e4120-f78e-484a-b6c8-267ca6b1816b' User entered '20 Nov 2020 00:55:52'	System	20 Nov 2020 05:55:55
	System	20 Nov 2020 05:55:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-27T11:37:54', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '959b1d56-a289-4bfb-bb2d-311d25b7dad5' User entered 'No (N)'	System	27 Nov 2020 16:41:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-27T11:40:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '959b1d56-a289-4bfb-bb2d-311d25b7dad5' User entered 'Yes (Y)'	System	27 Nov 2020 16:41:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-27T11:40:29', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '959b1d56-a289-4bfb-bb2d-311d25b7dad5'	System	27 Nov 2020 16:41:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 16:41:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-11-27T11:41:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '959b1d56-a289-4bfb-bb2d-311d25b7dad5' User entered '27 Nov 2020 11:41:31'	System	27 Nov 2020 16:41:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-04T13:52:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd34ec471-2c66-4070-981f-1bdea8a76a77' User entered 'No (N)'	System	04 Dec 2020 18:52:45
	System	04 Dec 2020 18:52:45

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-04T13:52:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd34ec471-2c66-4070-981f-1bdea8a76a77'	System	04 Dec 2020 18:52:45
User entered 'No (N)'	System	04 Dec 2020 18:52:45

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-04T13:52:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd34ec471-2c66-4070-981f-1bdea8a76a77' User entered '04 Dec 2020 13:52:42'	System	04 Dec 2020 18:52:45
	System	04 Dec 2020 18:52:45

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-14T00:49:40', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4e4bd6eb-f5ed-40ac-98cf-eb8b31622764' User entered 'No (N)'	System	14 Dec 2020 05:49:53
	System	14 Dec 2020 05:49:53

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-14T00:49:44', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4e4bd6eb-f5ed-40ac-98cf-eb8b31622764' User entered 'No (N)'	System	14 Dec 2020 05:49:53

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-14T00:49:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '4e4bd6eb-f5ed-40ac-98cf-eb8b31622764' User entered '14 Dec 2020 00:49:50'	System	14 Dec 2020 05:49:53
	System	14 Dec 2020 05:49:53

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-18T22:48:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd6f6335a-31e4-4b18-8d4e-84d29b308dfb' User entered 'No (N)'	System	19 Dec 2020 03:48:39

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-18T22:48:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd6f6335a-31e4-4b18-8d4e-84d29b308dfb' User entered 'No (N)'	System	19 Dec 2020 03:48:39

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-18T22:48:31', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'd6f6335a-31e4-4b18-8d4e-84d29b308dfb' User entered '18 Dec 2020 22:48:31'	System	19 Dec 2020 03:48:39
	System	19 Dec 2020 03:48:39

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-27T22:17:42', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ea180758-1221-4e07-8ce5-272e60ba47b8' User entered 'No (N)'	System	28 Dec 2020 03:17:51
	System	28 Dec 2020 03:17:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-27T22:17:46', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ea180758-1221-4e07-8ce5-272e60ba47b8' User entered 'No (N)'	System	28 Dec 2020 03:17:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2020-12-27T22:17:50', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ea180758-1221-4e07-8ce5-272e60ba47b8' User entered '27 Dec 2020 22:17:50'	System	28 Dec 2020 03:17:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-01T20:47:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24b95636-7d20-4f9f-81c5-7039bda5a10d' User entered 'No (N)'	System	02 Jan 2021 01:47:21
	System	02 Jan 2021 01:47:21

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-01T20:47:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24b95636-7d20-4f9f-81c5-7039bda5a10d' User entered 'No (N)'	System	02 Jan 2021 01:47:21
	System	02 Jan 2021 01:47:21

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-01T20:47:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '24b95636-7d20-4f9f-81c5-7039bda5a10d' User entered '01 Jan 2021 20:47:19'	System	02 Jan 2021 01:47:21
	System	02 Jan 2021 01:47:21

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-08T15:28:38', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '793a1a9c-0339-4ecc-a3e5-da6455c019ef' User entered 'No (N)'	System	08 Jan 2021 20:28:55
	System	08 Jan 2021 20:28:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-08T15:28:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '793a1a9c-0339-4ecc-a3e5-da6455c019ef' User entered 'No (N)'	System	08 Jan 2021 20:28:55
	System	08 Jan 2021 20:28:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-08T15:28:52', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '793a1a9c-0339-4ecc-a3e5-da6455c019ef' User entered '08 Jan 2021 15:28:52'	System	08 Jan 2021 20:28:55
	System	08 Jan 2021 20:28:55

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-19T12:38:19', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c1468b9c-8380-4ad3-bd3d-5ad8825b72b8' User entered 'No (N)'	System	19 Jan 2021 17:38:27

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-19T12:38:22', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c1468b9c-8380-4ad3-bd3d-5ad8825b72b8'	System	19 Jan 2021 17:38:27
User entered 'No (N)'	System	19 Jan 2021 17:38:27

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-19T12:38:25', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'c1468b9c-8380-4ad3-bd3d-5ad8825b72b8' User entered '19 Jan 2021 12:38:25'	System	19 Jan 2021 17:38:27

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-22T06:57:37', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '99b3bae6-fe2d-4414-8d64-9dd4f719bba2' User entered 'No (N)'	System	22 Jan 2021 11:57:46
	System	22 Jan 2021 11:57:46

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-22T06:57:41', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '99b3bae6-fe2d-4414-8d64-9dd4f719bba2' User entered 'No (N)'	System	22 Jan 2021 11:57:46

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-22T06:57:45', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '99b3bae6-fe2d-4414-8d64-9dd4f719bba2' User entered '22 Jan 2021 06:57:45'	System	22 Jan 2021 11:57:46
	System	22 Jan 2021 11:57:46

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-29T07:16:07', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f60696c3-a54c-4b6f-9555-22ce62156671' User entered 'No (N)'	System	29 Jan 2021 12:16:17

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-29T07:16:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f60696c3-a54c-4b6f-9555-22ce62156671' User entered 'No (N)'	System	29 Jan 2021 12:16:17
	System	29 Jan 2021 12:16:17

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-01-29T07:16:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'f60696c3-a54c-4b6f-9555-22ce62156671' User entered '29 Jan 2021 07:16:15'	System	29 Jan 2021 12:16:17
	System	29 Jan 2021 12:16:17

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-05T20:00:35', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e56b2c7-8351-4e60-bb19-43a6f28fd615' User entered 'Yes (Y)'	System	06 Feb 2021 01:02:51
	System	06 Feb 2021 01:02:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-05T20:00:43', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e56b2c7-8351-4e60-bb19-43a6f28fd615' User entered 'No (N)'	System	06 Feb 2021 01:02:51
	System	06 Feb 2021 01:02:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-05T20:01:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e56b2c7-8351-4e60-bb19-43a6f28fd615' User entered 'No (N)'	System	06 Feb 2021 01:02:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-05T20:02:10', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e56b2c7-8351-4e60-bb19-43a6f28fd615' User entered 'No (N)'	System	06 Feb 2021 01:02:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-05T20:02:33', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '5e56b2c7-8351-4e60-bb19-43a6f28fd615' User entered '05 Feb 2021 20:02:33'	System	06 Feb 2021 01:02:51
	System	06 Feb 2021 01:02:51

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-13T00:34:12', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ac77d9f7-8683-45c5-8125-d4725d10f671' User entered 'No (N)'	System	13 Feb 2021 05:38:12

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-13T00:34:15', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ac77d9f7-8683-45c5-8125-d4725d10f671' User entered 'No (N)'	System	13 Feb 2021 05:38:12

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-13T00:34:20', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'ac77d9f7-8683-45c5-8125-d4725d10f671' User entered '13 Feb 2021 00:34:20'	System	13 Feb 2021 05:38:12
	System	13 Feb 2021 05:38:12

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-19T00:32:59', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3ee115e2-30ee-4a8f-9549-14edcc9367c1' User entered 'No (N)'	System	19 Feb 2021 05:33:08

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-19T00:33:02', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3ee115e2-30ee-4a8f-9549-14edcc9367c1' User entered 'No (N)'	System	19 Feb 2021 05:33:08
	System	19 Feb 2021 05:33:08

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-19T00:33:05', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '3ee115e2-30ee-4a8f-9549-14edcc9367c1' User entered '19 Feb 2021 00:33:05'	System	19 Feb 2021 05:33:08
	System	19 Feb 2021 05:33:08

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-26T20:42:34-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1bc18d58-d3f0-469e-b2bc-8a1c4d05794c' User entered 'No (N)'	System	27 Feb 2021 01:42:43

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-26T20:42:38-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1bc18d58-d3f0-469e-b2bc-8a1c4d05794c' User entered 'No (N)'	System	27 Feb 2021 01:42:43

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-02-26T20:42:41-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '1bc18d58-d3f0-469e-b2bc-8a1c4d05794c' User entered '27 Feb 2021 01:42:41'	System	27 Feb 2021 01:42:43
	System	27 Feb 2021 01:42:43

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-05T16:24:05-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'abdc4e71-5aba-4219-96ba-615768c6f94b' User entered 'No (N)'	System	05 Mar 2021 21:24:15
	System	05 Mar 2021 21:24:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-05T16:24:08-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'abdc4e71-5aba-4219-96ba-615768c6f94b'	System	05 Mar 2021 21:24:15
User entered 'No (N)'	System	05 Mar 2021 21:24:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-05T16:24:13-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'abdc4e71-5aba-4219-96ba-615768c6f94b' User entered '05 Mar 2021 16:24:13'	System	05 Mar 2021 21:24:15
	System	05 Mar 2021 21:24:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-12T00:03:01-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '20c932e8-03a8-4b41-ada6-53cf25c70481' User entered 'No (N)'	System	12 Mar 2021 05:04:23
	System	12 Mar 2021 05:04:23

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-12T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '20c932e8-03a8-4b41-ada6-53cf25c70481' User entered 'No (N)'	System	12 Mar 2021 05:04:23

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-12T00:03:11-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '20c932e8-03a8-4b41-ada6-53cf25c70481'	System	12 Mar 2021 05:04:23
User entered '12 Mar 2021 00:03:11'	System	12 Mar 2021 05:04:23

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-21T16:43:01-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b509ee48-0a11-45c9-8049-bc0f2f65316e'	System	21 Mar 2021 20:43:15
User entered 'No (N)'	System	21 Mar 2021 20:43:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-21T16:43:08-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b509ee48-0a11-45c9-8049-bc0f2f65316e' User entered 'No (N)'	System	21 Mar 2021 20:43:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-21T16:43:12-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b509ee48-0a11-45c9-8049-bc0f2f65316e' User entered '21 Mar 2021 16:43:12'	System	21 Mar 2021 20:43:15
	System	21 Mar 2021 20:43:15

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-28T12:00:44-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8cea676b-9778-4e12-9b28-7ce27e74dfd8'	System	28 Mar 2021 16:02:56
User entered 'No (N)'	System	28 Mar 2021 16:02:56

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-28T12:01:16-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8cea676b-9778-4e12-9b28-7ce27e74dfd8'	System	28 Mar 2021 16:02:56
User entered 'No (N)'	System	28 Mar 2021 16:02:56

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-28T12:01:20-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '8cea676b-9778-4e12-9b28-7ce27e74dfd8' User entered '28 Mar 2021 12:01:20'	System	28 Mar 2021 16:02:56
	System	28 Mar 2021 16:02:56

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-03T00:26:21-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6b268731-570b-4444-8d3e-9e43d2fc1163'	System	03 Apr 2021 04:26:36
User entered 'No (N)'	System	03 Apr 2021 04:26:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-03T00:26:30-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6b268731-570b-4444-8d3e-9e43d2fc1163'	System	03 Apr 2021 04:26:36
User entered 'No (N)'	System	03 Apr 2021 04:26:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-03T00:26:33-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6b268731-570b-4444-8d3e-9e43d2fc1163'	System	03 Apr 2021 04:26:36
User entered '03 Apr 2021 00:26:33'	System	03 Apr 2021 04:26:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-11T17:45:17-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '02434212-49d6-4a3c-ba1c-8dbe704bfd21' User entered 'No (N)'	System	11 Apr 2021 21:45:33
	System	11 Apr 2021 21:45:33

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-11T17:45:03-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '02434212-49d6-4a3c-ba1c-8dbe704bfd21' User entered 'No (N)'	System	11 Apr 2021 21:45:33
	System	11 Apr 2021 21:45:33

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-11T17:45:27-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '02434212-49d6-4a3c-ba1c-8dbe704bfd21' User entered '11 Apr 2021 17:45:27'	System	11 Apr 2021 21:45:33
	System	11 Apr 2021 21:45:33

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-19T00:21:59-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '486b19bd-b88a-49bb-aed6-28d62308e752'	System	19 Apr 2021 04:22:18
User entered 'No (N)'	System	19 Apr 2021 04:22:18

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-19T00:22:03-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '486b19bd-b88a-49bb-aed6-28d62308e752'	System	19 Apr 2021 04:22:18
User entered 'No (N)'	System	19 Apr 2021 04:22:18

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-19T00:22:12-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '486b19bd-b88a-49bb-aed6-28d62308e752'	System	19 Apr 2021 04:22:18
User entered '19 Apr 2021 00:22:12'	System	19 Apr 2021 04:22:18

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-30T21:56:24-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b189a6a7-e2fe-41e6-b72c-a3a9d88073a1' User entered 'No (N)'	System	01 May 2021 01:56:36
	System	01 May 2021 01:56:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-30T21:56:27-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b189a6a7-e2fe-41e6-b72c-a3a9d88073a1'	System	01 May 2021 01:56:36
User entered 'No (N)'	System	01 May 2021 01:56:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-04-30T21:56:30-04:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: 'b189a6a7-e2fe-41e6-b72c-a3a9d88073a1'	System	01 May 2021 01:56:36
User entered '30 Apr 2021 21:56:30'	System	01 May 2021 01:56:36

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:58:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 17:58:42

US3542061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:58:42
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 17:58:42

US3542061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:04:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-03T14:16:46-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6c58d2f1-6b1b-48f4-b5a8-37136f0e1782'	System	03 Mar 2021 19:17:33
User entered 'Yes (Y)'	System	03 Mar 2021 19:17:33

US3542061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:04:57

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-03T14:16:58-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6c58d2f1-6b1b-48f4-b5a8-37136f0e1782'	System	03 Mar 2021 19:17:33
User entered 'Yes (Y)'	System	03 Mar 2021 19:17:33

US3542061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:04:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD243A99-E22D-4A0E-B933-9508F0F8734B)', Time: '2021-03-03T14:17:16-05:00', User OID: 'PatientReportedOutcome (US3542061)', ODM File OID: '6c58d2f1-6b1b-48f4-b5a8-37136f0e1782'	System	03 Mar 2021 19:17:33
User entered '03 Mar 2021 14:17:16'	System	03 Mar 2021 19:17:33

US3542061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:31
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:30:52

US3542061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:31
User entered '16 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:30:52
	(b) (4)	

US3542061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	17 Nov 2020 18:30:52

US3542061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:31
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:30:52

US3542061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:31
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:30:57
	(b) (4)	

US3542061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:28
User entered 'l'	System	17 Nov 2020 18:30:57

US3542061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:47:39

US3542061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:58:41
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 16:47:39

US3542061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:58:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 16:47:39

US3542061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:58:41
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 16:47:39

US3542061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:47:45

US3542061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User entered 'l'	System	22 Dec 2020 16:47:45

US3542061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:11:08
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 17:26:37

US3542061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:11:08
User entered '19 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 17:26:37

US3542061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:11:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 17:26:37

US3542061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:11:08
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Jan 2021 17:26:37

US3542061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:11:08
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 17:26:42

US3542061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User entered 'l'	System	22 Jan 2021 17:26:42

US3542061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:37:33

US3542061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '17 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:37:33

US3542061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:37:33

US3542061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:37:33

US3542061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:37:38

US3542061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:46
User entered 'I'	System	18 Feb 2021 15:37:38

US3542061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:30:10

US3542061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 17:30:10

US3542061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:33:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:31:54

US3542061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:33:03
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:31:54

US3542061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:33:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:31:54

US3542061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:33:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:31:54

US3542061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:33:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:32:01

US3542061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 17:32:01

US3542061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:26:54

US3542061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:26:54

US3542061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:26:54

US3542061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 20:26:54

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:40:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:49:46

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:40:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:49:46

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:26:14
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:26:14
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'I'	System	08 Jan 2021 20:27:18

US3542061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'I'	System	08 Jan 2021 20:27:18

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered empty.	System	08 Jan 2021 20:29:39
DataPoint set to visible.	System	08 Jan 2021 20:27:18

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered empty.	System	08 Jan 2021 20:29:39
DataPoint set to visible.	System	08 Jan 2021 20:27:18

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '10:28'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered '07 Jan 2021 10:28'	System	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '98.0' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '59'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'bpm'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'breaths/min'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '110'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'mmHg'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '72'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'mmHg'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered empty.	System	08 Jan 2021 20:29:39
DataPoint set to visible.	System	08 Jan 2021 20:27:18

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '11:09'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered '07 Jan 2021 11:09'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '98.1' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '57'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'bpm'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'breaths/min'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '122'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'mmHg'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '75'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'mmHg'	System	08 Jan 2021 20:29:39

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:38

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:38

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'mRNA-1273'	System	08 Jan 2021 20:28:30
DataPoint set to visible.	System	08 Jan 2021 20:27:18

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '10:39'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered '07 Jan 2021 10:39'	System	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'ONCE'	System	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 20:28:30

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:32

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:32

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '10:32'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:32

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered '07 Jan 2021 10:32'	System	08 Jan 2021 20:27:32

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:43

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '07 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:43

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered '10:35'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:43

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:57

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered '07 Jan 2021 10:35'	System	08 Jan 2021 20:27:43

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:44
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 20:27:53

US3542061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:20
User entered 'l'	System	08 Jan 2021 20:27:53

US3542061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:57:24

US3542061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:57:24

US3542061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:57:24

US3542061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:57:24

US3542061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:57:29

US3542061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User entered 'l'	System	14 Jan 2021 16:57:29

US3542061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:40
User entered 'I'	System	14 Jan 2021 16:57:29
DataPoint set to visible.	System	14 Jan 2021 16:57:29

US3542061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:35:39

US3542061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:35:39

US3542061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:35:39

US3542061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'OLD29'	System	05 Feb 2021 17:35:39

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '10:25'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered '04 Feb 2021 10:25'	System	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '98.4' F	(b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '71'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'bpm'	System	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'breaths/min'	System	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '115'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'mmHg'	System	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '76'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'mmHg'	System	05 Feb 2021 17:36:12

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '11:22'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered '04 Feb 2021 11:22'	System	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '98' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '69'	(b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'bpm'	System	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'breaths/min'	System	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '130'	(b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'mmHg'	System	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '82'	(b) (4), (b) (6)	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'mmHg'	System	05 Feb 2021 17:36:48

US3542061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:00

US3542061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:00

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'mRNA-1273'	System	05 Feb 2021 17:37:20
DataPoint set to visible.	System	14 Jan 2021 16:57:29

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered '10:52'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered '04 Feb 2021 10:52'	System	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 05:57:24
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Participant specified he wanted the injection in the left arm. Added to protocol deviation log' (Site from System).	Elissa Malkin (b) (4) (b) (4)	17 Feb 2021 21:05:41
Amendment Manager: User opened query 'Treatment System Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		17 Feb 2021 01:27:46
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Feb 2021 01:52:19
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'ONCE'	System	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 17:37:20

US3542061

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:52:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:37:24

US3542061

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:15
User entered 'l'	System	05 Feb 2021 17:37:24

US3542061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:27:42

US3542061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:01:07
User entered '11 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 17:27:42

US3542061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 17:27:42

US3542061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:01:07
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 17:27:42

US3542061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:27:34

US3542061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:13:19
User entered 'l'	System	12 Feb 2021 17:27:34

US3542061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:37:36

US3542061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:37:36
	(b) (4)	

US3542061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:37:36

US3542061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered 'OLD57'	System	09 Mar 2021 16:37:36

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered empty.	System	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01
	(b) (4)	

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01
	(b) (4)	

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01
	(b) (4)	

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered empty.	System	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered empty.	System	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered empty.	System	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered empty.	System	09 Mar 2021 16:38:01

US3542061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30

US3542061

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:37:42

US3542061

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:37:42

US3542061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:37:55

US3542061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:37:55

US3542061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
User entered '11:42'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:37:55

US3542061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:30
User entered '08 Mar 2021 11:42'	System	09 Mar 2021 16:37:55

US3542061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:04:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:57
User closed query 'Per CDM: Per sponsor review, Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue and Nausea/Vomiting lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:40:23
Query 'Per CDM: Per sponsor review, Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue and Nausea/Vomiting lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'Updated as requested.' (Site from DM).	David Diemert (b) (4) (b) (4)	19 Apr 2021 20:12:59
User opened query 'Per CDM: Per sponsor review, Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue and Nausea/Vomiting lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:52:03
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:53:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 18:55:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 18:55:42
Data point term sent to Coder	System	31 Aug 2020 18:54:54
User entered 'Dizziness'	Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '26 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '10:23'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User entered '26 Aug 2020 10:23'	System	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '26 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '10:38'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User entered '26 Aug 2020 10:38'	System	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'Related (RELATED)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'Related (RELATED)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'None (NONE)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'l'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 18:54:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:32:11
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User entered '0'	System	31 Aug 2020 18:54:14

US3542061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11
User entered '0'	System	31 Aug 2020 18:54:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:45:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:42:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:42:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:41:43
Data point term sent to Coder	System	21 Oct 2020 19:40:37
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Corrected.' (Site from DM).	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:39:51
Coding entries removed.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:39:45
Signature has been broken.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:39:45
User entered 'JOINT ACHES, Generalized' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:39:45
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:09:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 03:11:05

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:22:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:22:34
Data point term sent to Coder	System	17 Sep 2020 15:22:03
User entered 'joint aches'	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	09 Apr 2021 18:50:16
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	09 Apr 2021 16:38:14
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	David Diemert (b) (4)	09 Apr 2021 16:38:14
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:50:51
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'Started outside of the 7-day post-injection period, therefore not solicited.' (Site from DM).	David Diemert (b) (4)	21 Oct 2020 19:41:02
	(b) (4)	
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:09:58
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	09 Apr 2021 18:50:16
Signature has been broken.	(b) (4) David Diemert (b) (4)	09 Apr 2021 16:38:14
User entered '27 Aug 2020' reason for change: Per Query Resolution	(b) (4) David Diemert (b) (4)	09 Apr 2021 16:38:14
User closed query 'Per DM CLR: RQ: Response noted, however, the start should be reconciled with the date the subject first felt this symptom which was on 27 AUG 2020 per eDiary. Also review if should be a solicited adverse reaction. Please update and reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:20:09
Query 'Per DM CLR: RQ: Response noted, however, the start should be reconciled with the date the subject first felt this symptom which was on 27 AUG 2020 per eDiary. Also review if should be a solicited adverse reaction. Please update and reconcile as appropriate. Otherwise, clarify.' answered with 'Per eCRF guidelines, the dates of the AE are those dates not recorded in the eDiary ' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	17 Dec 2020 18:28:32
User opened query 'Per DM CLR: RQ: Response noted, however, the start should be reconciled with the date the subject first felt this symptom which was on 27 AUG 2020 per eDiary. Also review if should be a solicited adverse reaction. Please update and reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 14:52:23
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:07:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'This is a new event after the previous one ended.' (Site from DM).	David Diemert (b) (4)	21 Oct 2020 19:41:33
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:10:06
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '09 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	09 Apr 2021 18:50:16
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	09 Apr 2021 16:38:14
	(b) (4)	
User entered '08:00' reason for change: Per Query Resolution	David Diemert (b) (4)	09 Apr 2021 16:38:14
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	24 Sep 2020 03:11:05
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User entered '27 Aug 2020 08:00'	System	09 Apr 2021 16:38:14
User entered empty.	System	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '19 Sep 2020' reason for change: New Information	(b) (4)	
	Taylor Ladson (b) (4)	23 Sep 2020 16:21:39
User entered '09 Sep 2020'	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	09 Apr 2021 18:50:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Signature has been broken.	System	09 Apr 2021 16:42:23
User entered '23:59' reason for change: Per Query Resolution	David Diemert (b) (4)	09 Apr 2021 16:42:23
User opened query 'Data is required. Please provide.' (Site from System).	David Diemert (b) (4)	09 Apr 2021 16:42:23
User signature succeeded.	System	09 Apr 2021 16:38:14
User entered empty.	David Diemert (b) (4)	24 Sep 2020 03:11:05
	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User entered '19 Sep 2020 23:59'	System	09 Apr 2021 16:42:23
User entered empty.	System	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:20:37
User entered 'Related (RELATED)' reason for change: New Information	Taylor Ladson (b) (4)	23 Sep 2020 16:20:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Sep 2020 15:21:35
	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Sep 2020 16:20:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:20:37
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Taylor Ladson (b) (4) (b) (4)	23 Sep 2020 16:20:37
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 15:21:35
User entered empty.	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'None (NONE)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: New Information	System	23 Sep 2020 16:20:37
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Taylor Ladson (b) (4)	23 Sep 2020 16:20:37
User entered '0'	(b) (4)	
	System	17 Sep 2020 15:21:35
	Taylor Ladson (b) (4)	17 Sep 2020 15:21:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User entered '0'	System	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15
User entered '0'	System	17 Sep 2020 15:21:35

US3542061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19

US3542061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	20 Oct 2020 03:37:04
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	David Diemert (b) (4)	16 Oct 2020 21:03:29
answered with 'This participant was called by PI and symptom was determined to not be consistent with COVID-19 and had resolved by the time of the call. No illness visit was warranted.'	(b) (4)	
(Site from DM).		
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	06 Oct 2020 09:49:22
(Site from DM).		
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:23:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:23:39
Data point term sent to Coder	System	17 Sep 2020 15:23:04
User entered 'chills'	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

US3542061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '09 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

US3542061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User entered empty.	System	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '16 Sep 2020' reason for change: New Information	(b) (4)	
	Taylor Ladson (b) (4)	23 Sep 2020 16:21:24
User entered '09 Sep 2020'	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User entered empty.	System	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:21:24
User entered 'Related (RELATED)' reason for change: New Information	Taylor Ladson (b) (4)	23 Sep 2020 16:21:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Sep 2020 15:22:20
	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:21:24
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Taylor Ladson (b) (4)	23 Sep 2020 16:21:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Sep 2020 15:22:20
	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered 'None (NONE)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	23 Sep 2020 16:21:24
User entered '1' reason for change: New Information	Taylor Ladson (b) (4)	23 Sep 2020 16:21:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Sep 2020 15:22:20
User entered '0'	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Sep 2020 13:29:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Hannah Yellin (b) (4)	20 Sep 2020 13:29:53
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 15:22:20
User entered empty.	Taylor Ladson (b) (4)	17 Sep 2020 15:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:11:05
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User entered '0'	System	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19
User entered '0'	System	17 Sep 2020 15:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:47:31
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:36:29
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:49:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:49:29
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	02 Nov 2020 20:11:26
Data point term sent to Coder	System	02 Nov 2020 20:11:05
Coding entries removed.	Elissa Malkin (b) (4)	02 Nov 2020 20:10:47
Signature has been broken.	Elissa Malkin (b) (4)	02 Nov 2020 20:10:47
User entered 'BODY ACHES (generalized)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	02 Nov 2020 20:10:47
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:12:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:23:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:23:52
Data point term sent to Coder	System	09 Oct 2020 16:18:39
User entered 'Body aches'	Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User entered empty.	System	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User entered empty.	System	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

US3542061

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 14:44:14
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	05 Jan 2021 14:44:14
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Oct 2020 19:41:43
	(b) (4)	
User entered 'None (NONE)'	Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User entered '0'	System	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22
User entered '0'	System	09 Oct 2020 16:17:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM). Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Participant was assessed by telehealth visit. Symptoms lasted under 30 minutes in total so Illness Visit was judged to be not indicated.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:27:07
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	David Diemert (b) (4)	16 Feb 2021 18:12:16
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:29:19
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 16:23:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 16:23:52
Data point term sent to Coder	System	09 Oct 2020 16:18:41
User entered 'Chills'	Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User entered empty.	System	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User entered empty.	System	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 14:44:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	05 Jan 2021 14:44:24
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Oct 2020 19:41:43
	(b) (4)	
User entered 'None (NONE)'	Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:18:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User entered '0'	System	09 Oct 2020 16:18:30

US3542061

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User entered '0'	System	09 Oct 2020 16:18:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 16:26:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 16:26:12
Data point term sent to Coder	System	09 Oct 2020 16:19:42
User entered 'Fatigue'	Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User entered empty.	System	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User entered empty.	System	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

US3542061

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 14:44:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	05 Jan 2021 14:44:39
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Oct 2020 19:41:43
	(b) (4)	
User entered 'None (NONE)'	Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:04:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User entered '0'	System	09 Oct 2020 16:19:00

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30
User entered '0'	System	09 Oct 2020 16:19:00

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Diaphoresis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 16:25:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 16:25:29
Data point term sent to Coder	System	09 Oct 2020 16:19:42
User entered 'Diaphoresis'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User entered empty.	System	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User entered empty.	System	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 14:44:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	05 Jan 2021 14:44:50
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'None (NONE)'	(b) (4)	
	Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User entered '0'	System	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50
User entered '0'	System	09 Oct 2020 16:19:33

US3542061

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:50

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:41:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:26:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:26:04
Data point term sent to Coder	System	09 Oct 2020 16:20:43
User entered 'Nausea'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User entered empty.	System	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '07 Oct 2020'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User entered empty.	System	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

US3542061

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 14:45:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	05 Jan 2021 14:45:01
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'None (NONE)'	(b) (4)	
	Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Form: Adverse Events (8)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered '0'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:41:43
User entered empty.	(b) (4) Hannah Yellin (b) (4)	09 Oct 2020 16:20:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User entered '0'	System	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56
User entered '0'	System	09 Oct 2020 16:20:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:56

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 04:04:02
Un-reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 18:39:54
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 18:39:54
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 18:39:54
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Mar 2021 18:39:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:12:52
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 21:45:29
User entered	System	18 Feb 2021 21:45:20
'USA-US084-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 21:45:20

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	06 Apr 2021 15:06:56
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 13:07:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 13:07:43
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:50:54
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'Fine, whatever. As a physician, I have no idea what "worsening nephrolithiasis" is, since this disease is typically episodic. But to make this query go away (hopefully forever), I'll do as you ask. Change made.' (Site from DM).	David Diemert (b) (4)	05 Apr 2021 14:23:18
Data point term sent to Coder	System	05 Apr 2021 14:21:24
DataPoint Un-verified.	David Diemert (b) (4)	05 Apr 2021 14:21:21
Coding entries removed.	David Diemert (b) (4)	05 Apr 2021 14:21:21
Signature has been broken.	David Diemert (b) (4)	05 Apr 2021 14:21:21
User entered 'Worsened RIGHT NEPHROLITHIASIS' reason for change: Per Query Resolution	David Diemert (b) (4)	05 Apr 2021 14:21:21
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:12:54
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Unilateral renal calculus - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 17:48:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 17:48:52
Data point term sent to Coder	System	19 Feb 2021 17:48:08
Coding entries removed.	Erika Faust (b) (4)	19 Feb 2021 17:47:14
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:47:14
User entered 'Right NEPHROLITHIASIS' reason for change: New Information	(b) (4)	
User signature succeeded.	Erika Faust (b) (4)	19 Feb 2021 17:47:14
	(b) (4)	
	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 17:01:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 17:01:05
Data point term sent to Coder	System	14 Jan 2021 17:00:04
User entered 'Nephrolithiasis'	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:12:57
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:13:00
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:13:02
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:13:06
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '09 Jan 2021'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:05
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 16:59:17

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:35:52
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:35:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'Will do.' (Site from Safety).	David Diemert (b) (4) (b) (4)	23 Mar 2021 18:28:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Still ongoing. Will update when resolved.' (Site from Safety).	David Diemert (b) (4) (b) (4)	23 Mar 2021 18:28:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:31:33
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:24:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:24:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Jan 2021 02:40:52
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:32
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:33
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:14
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:16
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Feb 2021 15:20:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Feb 2021 15:20:08
Signature has been broken.	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:21
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:23
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
User entered '0' reason for change: New Information	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:30
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
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), (b) (6)	19 Feb 2021 05:57:47
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 with 'Box is checked and hospital dates are entered.' (Site from System).	Caroline Thoreson (b) (4)	18 Feb 2021 15:21:21
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Feb 2021 15:20:31
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Feb 2021 15:20:31
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 Feb 2021 15:20:31
Signature has been broken.	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:31
	(b) (4)	
User entered '1' reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User signature succeeded.	System	18 Feb 2021 15:20:08
	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
User entered empty; reason for change New Information	David Diemert (b) (4)	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 15:15:36
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Signature has been broken.	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User entered '9 Feb 2021' reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 18:28:12
	(b) (4)	
User entered empty; reason for change New Information	David Diemert (b) (4)	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 15:15:37
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Signature has been broken.	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User entered '10 Feb 2021' reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:39
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:43
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:48
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:58
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:50
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:55
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:15:53
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:49:03
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' answered with 'We have been instructed to enter "not applicable" if the event occurred AFTER the 2 doses of IP/placebo were given during the blinded phase of the study. ' (Site from Safety).	David Diemert (b) (4) (b) (4)	08 Mar 2021 23:05:38
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:25:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Jan 2021 02:40:52
User entered 'Not Applicable (NOT APPLICABLE)'	Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:16:02
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:16:04
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:16:06
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User entered '1' reason for change: New Information	Caroline Thoreson (b) (4)	18 Feb 2021 15:20:08
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	14 Jan 2021 16:59:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:16:09
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:16:11
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Jan 2021 16:59:17

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = RECEIVED DOSE OF AUGMENTIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 11:40:56
User closed query 'PV Query: Please consider whether this event meets SAE reporting criteria considering that hospitalization did not last for more than 24 hours as reported with admission and discharge on 09Feb2021 per the medical records. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:36:39
User closed query 'PV Query: Please consider whether to update the subject's medical history to include previous history of nephrolithiasis as noted in the medical records. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:36:09
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:36:01
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
User entered 'UNBLINDED AND RECEIVED FIRST DOSE OF MRNA-1273 ON 07 JAN 2021, THEN PT WAS ADMITTED 9-FEB TO 9-FEB-2021 AT WALTER REED MEDICAL CENTER. HE UNDERWENT NEPHROLITHOTOMY AND RIGHT URETERAL STENT PLACEMENT ON 9-FEB-2021. HE WAS DISCHARGED HOME ON 9-FEB-2021. HE HAS BEEN TAKING OXYCODONE, MOTRIN AND TYLENOL FOR POST-PROCEDURE SYMPTOMS. MEDICAL RECORDS OBTAINED AND FAXED TO MODERNA SAFETY.' reason for change: Per Query Resolution	David Diemert (b) (4)	23 Mar 2021 18:28:12

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User		Time (GMT)
Query 'PV Query: Please consider whether this event meets SAE reporting criteria considering that hospitalization did not last for more than 24 hours as reported with admission and discharge on 09Feb2021 per the medical records. ' answered with 'Upon review of hospital records, this is correct. Same day admission/discharge, so will delete SAE. ' (Site from Safety).	David Diemert (b) (4)	(b) (4)	23 Mar 2021 18:26:45
Query 'Per DM CLR: Narrative = RECEIVED DOSE OF AUGMENTIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Did not receive Augmentin but rather, pre-procedure cefazolin x 1. Recorded in Con Med log.' (Site from DM).	David Diemert (b) (4)	(b) (4)	23 Mar 2021 15:20:02
User entered 'UNBLINDED AND RECEIVED FIRST DOSE OF MRNA-1273 ON 07 JAN 2021, THEN PT WAS ADMITTED 9-FEB TO 10-FEB-2021 AT WALTER REED MEDICAL CENTER. HE UNDERWENT NEPHROLITHOTOMY AND RIGHT URETERAL STENT PLACEMENT ON 9-FEB-2021. HE WAS DISCHARGED HOME ON 10-FEB-2021. HE HAS BEEN TAKING OXYCODONE, MOTRIN AND TYLENOL FOR POST-PROCEDURE SYMPTOMS. MEDICAL RECORDS obtained and faxed to Moderna Safety.' reason for change: Per Query Resolution	David Diemert (b) (4)	(b) (4)	23 Mar 2021 15:19:09
Query 'PV Query: Please consider whether to update the subject's medical history to include previous history of nephrolithiasis as noted in the medical records. ' answered with 'Done' (Site from Safety).	David Diemert (b) (4)	(b) (4)	23 Mar 2021 12:22:42
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	(b) (4)	23 Mar 2021 12:19:21
DataPoint Un-verified.	David Diemert (b) (4)	(b) (4)	23 Mar 2021 12:19:04
Signature has been broken.	David Diemert (b) (4)	(b) (4)	23 Mar 2021 12:19:04

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Unblinded and received first dose of mRNA-1273 on 07 Jan 2021, then PT WAS ADMITTED 9-FEB TO 10-FEB-2021 AT WALTER REED MEDICAL CENTER. HE UNDERWENT NEPHROLITHOTOMY AND RIGHT URETERAL STENT PLACEMENT ON 9-FEB-2021. HE WAS DISCHARGED HOME ON 10-FEB-2021. HE HAS BEEN TAKING OXYCODONE, MOTRIN AND TYLENOL FOR POST-PROCEDURE SYMPTOMS. HE STATES HE ALSO RECEIVED DOSE OF AUGMENTIN (UNKNOWN DAY/DOSE). WILL ATTEMPT TO OBTAIN MEDICAL RECORDS.' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	23 Mar 2021 12:19:04
User opened query 'PV Query: Please consider whether this event meets SAE reporting criteria considering that hospitalization did not last for more than 24 hours as reported with admission and discharge on 09Feb2021 per the medical records. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 15:56:09
User opened query 'PV Query: Please consider whether to update the subject's medical history to include previous history of nephrolithiasis as noted in the medical records. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 15:55:45
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 07 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 15:55:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:18:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:47:03
User opened query 'Per DM CLR: Narrative = RECEIVED DOSE OF AUGMENTIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:26:09

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Pre-procedure COVID-19 testing result was not included in the discharge or hospital records received from the hospital.' (Site from Safety).	David Diemert (b) (4) (b) (4)	08 Mar 2021 23:06:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:25:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	19 Feb 2021 17:25:02
Signature has been broken.	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:20:08
User entered 'Pt was admitted 9-FEB to 10-FEB-2021 at Walter Reed Medical Center. He underwent nephrolithotomy and right ureteral stent placement on 9-FEB-2021. He was discharged home on 10-FEB-2021. He has been taking oxycodone, Motrin and Tylenol for post-procedure symptoms. He states he also received dose of Augmentin (unknown day/dose). Will attempt to obtain medical records.' reason for change: New Information	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:20:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Jan 2021 02:40:52
User entered empty.	Erika Faust (b) (4) (b) (4)	14 Jan 2021 16:59:17

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 18:28:12
User entered '1'	System	18 Feb 2021 15:20:08
User entered '0'	System	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (9)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	14 Jan 2021 16:59:17

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:10:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:10:44
Data point term sent to Coder	System	19 Apr 2021 20:09:52
Coding entries removed.	David Diemert (b) (4)	19 Apr 2021 20:09:14
User entered 'Fatigue' reason for change: Data Entry Error	David Diemert (b) (4)	19 Apr 2021 20:09:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 18:44:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 18:44:48
Data point term sent to Coder	System	19 Apr 2021 18:43:45
User entered 'Nausea'	David Diemert (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '26 Aug 2020'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '21:00'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User entered '26 Aug 2020 21:00'	System	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '11 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	19 Apr 2021 20:09:14
User entered '23:59' reason for change: Data Entry Error	David Diemert (b) (4)	19 Apr 2021 20:09:14
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:43:05
User entered empty.	David Diemert (b) (4)	19 Apr 2021 18:43:05
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User entered '11 Sep 2020 23:59'	System	19 Apr 2021 20:09:14
User entered empty.	System	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Related (RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'None (NONE)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User entered '0'	System	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58
User entered '0'	System	19 Apr 2021 18:43:05

US3542061

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:58

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:11:46
Data point term sent to Coder	System	19 Apr 2021 20:10:53
User entered 'Nausea'	David Diemert (b) (4)	19 Apr 2021 20:10:49

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '01 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User entered empty.	System	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '02 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User entered empty.	System	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'None (NONE)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 12:55:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User entered '0'	System	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13
User entered '0'	System	19 Apr 2021 20:10:49

US3542061

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:26:13

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'USA-US084-2021-mRNA-1273-P301000010'	(b) (4) System	21 Apr 2021 15:50:45
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 15:50:45

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 17:45:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 17:45:42
Data point term sent to Coder	System	20 Apr 2021 17:44:45
User entered 'Acute pancreatitis'	David Diemert (b) (4) (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'No (N)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'No (N)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '06 Apr 2021'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered empty.	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'No (N)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '16 Apr 2021'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered empty.	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'l'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '08 Apr 2021'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '16 Apr 2021'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'No (N)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered empty.	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'l'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:16
User closed query 'As per SAE ACUTE PANCREATITIS, ConMed procedure was conducted. Can you please verify and Check this box.Thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 16:25:43
Query 'As per SAE ACUTE PANCREATITIS, ConMed procedure was conducted. Can you please verify and Check this box.Thanks.' answered with 'Added.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 16:20:34
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 16:20:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 16:20:13
User opened query 'As per SAE ACUTE PANCREATITIS, ConMed procedure was conducted. Can you please verify and Check this box.Thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 16:32:58
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered '0'	David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered empty.	(b) (4) David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	02 May 2021 21:15:39
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:42:23
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:42:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'This has already been done.' (Site from Safety).	David Diemert (b) (4) (b) (4)	30 Apr 2021 03:30:22
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID-19 testing is not recorded in hospital summary.' (Site from Safety).	David Diemert (b) (4) (b) (4)	30 Apr 2021 03:30:03
Signature has been broken.	David Diemert (b) (4) (b) (4)	30 Apr 2021 03:29:26

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS ADMITTED TO AN OUTSIDE HOSPITAL ON 08APR2021 FOR MEDICAL MANAGEMENT OF ACUTE PANCREATITIS (SYMPTOMS STARTED ON 06APR2021). HOSPITAL DISCHARGE RECORDS WERE RECEIVED ON 22APR2021. PARTICIPANT WAS DIAGNOSED WITH ACUTE PANCREATITIS DUE TO TYPICAL EPIGASTRIC PAIN RADIATING POSTERIORLY ASSOCIATED WITH ELEVATED LIPASE 3X UPPER LIMIT OF NORMAL. ABDOMINAL ULTRASOUND PERFORMED ON 09APR2021 WAS UNREMARKABLE AND CT ABDOMEN ON 08APR2021 DID NOT REVEAL ANY POTENTIAL CAUSE OF PANCREATITIS (NORMAL APPEARING PANCREAS, GALLBLADDER AND BILIARY TREE). EGD SHOWED SMALL GASTRIC ULCER AND MULTIPLE HEALING ULCERS. RESPONDED TO CONSERVATIVE MANAGEMENT (PAIN MANAGEMENT WITH OXYCODONE AND INITIATION OF PANTOPRAZOLE). DISCHARGE HOME WAS ON 16APR2021. There are no records of COVID-19 testing being done.'	David Diemert (b) (4)	30 Apr 2021 03:29:26
reason for change: New Information		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:07:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:07:00
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 21:40:49
Signature has been broken.	David Diemert (b) (4)	22 Apr 2021 21:17:13

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS ADMITTED TO AN OUTSIDE HOSPITAL ON 08APR2021 FOR MEDICAL MANAGEMENT OF ACUTE PANCREATITIS (SYMPTOMS STARTED ON 06APR2021). HOSPITAL Discharge RECORDS were received on 22APR2021. Participant was diagnosed with acute pancreatitis due to typical epigastric pain radiating posteriorly associated with elevated lipase 3x upper limit of normal. Abdominal ultrasound performed on 09APR2021 was unremarkable and CT abdomen on 08APR2021 did not reveal any potential cause of pancreatitis (normal appearing pancreas, gallbladder and biliary tree). EGD showed small gastric ulcer and multiple healing ulcers. Responded to conservative management (pain management with oxycodone and initiation of pantoprazole). DISCHARGE HOME WAS ON 16APR2021.' reason for change: New Information User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 21:17:13
	David Diemert (b) (4)	21 Apr 2021 02:49:41
User entered 'Participant was admitted to an outside hospital on 08APR2021 for medical management of acute pancreatitis (Symptoms started on 06APR2021). Hospital records have been requested. The narrative will be updated when received. Discharge home was on 16APR2021.'	David Diemert (b) (4)	20 Apr 2021 17:44:29

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 17:44:29

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Apr 2021 19:32:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 19:32:56
Data point term sent to Coder	System	22 Apr 2021 19:32:08
User entered 'Worsening of prostate cancer'	Hannah Yellin (b) (4) (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '04 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:31:28

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:31:28
	(b) (4)	

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Apr 2021 19:31:28

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer, LLT: Peptic ulcer disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 18:29:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:29:06
Data point term sent to Coder	System	23 Apr 2021 18:28:23
User entered 'Peptic ulcer DISEASE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:27:59
Data point term sent to Coder	System	23 Apr 2021 18:27:20
User entered 'Pepticular disease'	(b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 18:26:59

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Groin abscess, LLT: Groin abscess - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 18:31:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:31:52
Data point term sent to Coder	System	23 Apr 2021 18:31:25
User entered 'Groin Abscess'	(b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 18:31:12

US3542061

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:04:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 18:31:12

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:04:57

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:57
User closed query 'Per CDM Re-query: Patient confirmed to received facial cosmetic injections. Please enter cosmetic injections taken either on the following pages as applicable Medical History form, Concomitant Procedures or Concomitant Medications. Review and Update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:57:17
Query 'Per CDM Re-query: Patient confirmed to received facial cosmetic injections. Please enter cosmetic injections taken either on the following pages as applicable Medical History form, Concomitant Procedures or Concomitant Medications. Review and Update accordingly.' answered with 'Injection has already been entered in Med History eCRF. No further action is needed on our part.' (Site from DM).	David Diemert (b) (4) (b) (4)	31 Mar 2021 12:59:35
User opened query 'Per CDM Re-query: Patient confirmed to received facial cosmetic injections. Please enter cosmetic injections taken either on the following pages as applicable Medical History form, Concomitant Procedures or Concomitant Medications. Review and Update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:48:16
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:48:16

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:04:57

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Per sponsor instruction, this query is not needed' (Site from DM).	David Diemert (b) (4) (b) (4)	23 Mar 2021 17:59:40
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:01:55
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:01:41
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:30:04
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:16:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:53:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: BICALUTAMIDE, PRODUCTSYNONYM: CASODEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:04
Data point term sent to Coder	System	27 Aug 2020 17:55:33
User entered 'casodex'	Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'prostate cancer'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '150'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	31 Aug 2020 18:50:11
User entered '08 Aug 2020'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:55:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
	(b) (4)	
Signature has been broken.	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	27 Aug 2020 17:55:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
	(b) (4)	
Signature has been broken.	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
	(b) (4)	
User entered '13 Apr 2021' reason for change: Data Entry Error	Hannah Yellin (b) (4)	22 Apr 2021 19:32:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	27 Aug 2020 17:55:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:55:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:55:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: GONADOTROPIN RELEASING HORMONE ANALOGUES, PRODUCT: LEUPRORELIN ACETATE, PRODUCTSYNONYM: LUPRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:21
Data point term sent to Coder	System	27 Aug 2020 17:56:37
User entered 'lupron'	Taylor Ladson (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'prostate cancer'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'unk'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	31 Aug 2020 18:50:44
User entered 'once daily (QD)'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:55:56
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '08 Jul 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '08 Jul 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
User entered empty.	System	31 Aug 2020 18:50:44
User entered 'l'	System	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
User entered empty.	System	31 Aug 2020 18:50:44
User entered 'l'	System	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:37:47
User entered empty.	System	31 Aug 2020 18:50:44
User entered '804 (804)'	System	27 Aug 2020 17:55:56

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:50
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:44
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:31
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:44:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:23
Data point term sent to Coder	System	27 Aug 2020 17:56:38
User entered 'metformin'	Taylor Ladson (b) (4)	27 Aug 2020 17:56:31
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:52
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:46
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'diabetes'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:55
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '1000'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:56
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:58
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:03
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:43
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:05
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:08
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '27 Jul 2020' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	31 Aug 2020 18:51:50
User entered '07 Jul 2020'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:56:31
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:56:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:21
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE, PRODUCTSYNONYM: LOTREL [AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:26
Data point term sent to Coder	System	27 Aug 2020 17:57:38
User entered 'lotrel'	Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:25
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'hypertension'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'unk'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:30
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:31
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:32
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:36
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:38
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2007'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
	(b) (4)	
Signature has been broken.	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 14:26:41
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	27 Aug 2020 17:57:19
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
	(b) (4)	
Signature has been broken.	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
	(b) (4)	
User entered '15 Apr 2021' reason for change: New Information	Hannah Yellin (b) (4)	22 Apr 2021 19:32:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:43
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	27 Aug 2020 17:57:19
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:57:19

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:44:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:37
Data point term sent to Coder	System	27 Aug 2020 17:58:40
User entered 'myrbetriq'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'overactive bladder'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '25'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un Aug 2020'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:44
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:58:10

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:12:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:12:46
Data point term sent to Coder	System	14 Dec 2020 20:11:56
Coding entries removed.	Erika Faust (b) (4)	14 Dec 2020 20:11:15
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	27 Aug 2020 19:44:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:38
Data point term sent to Coder	System	27 Aug 2020 17:58:43
User entered 'baby aspirin'	Taylor Ladson (b) (4)	27 Aug 2020 17:58:40
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:15:20
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	14 Dec 2020 20:11:15
User entered 'CORONARY ARTERY DISEASE'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	14 Dec 2020 20:11:15
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered 'coronary heart disease'	Taylor Ladson (b) (4)	27 Aug 2020 17:58:40
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '81'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2007'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:58:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:56
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:41
Data point term sent to Coder	System	27 Aug 2020 17:59:44
User entered 'lipitor'	Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:58
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:00
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'elevated cholesterol'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:02
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
User entered '80' reason for change: New Information	David Diemert (b) (4)	23 Mar 2021 13:42:01
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 13:41:53
User entered '40' reason for change: New Information	David Diemert (b) (4)	23 Mar 2021 13:41:53
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'unk'	Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:03
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 13:41:53
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	23 Mar 2021 13:41:53
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User entered 'Other (OTHER)'	Taylor Ladson (b) (4)	27 Aug 2020 17:59:21
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:05
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 13:41:53
	(b) (4)	
User entered empty; reason for change Data Entry Error	David Diemert (b) (4)	23 Mar 2021 13:41:53
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	27 Aug 2020 18:00:08
User entered 'unknown' reason for change: Data Entry Error	Taylor Ladson (b) (4)	27 Aug 2020 18:00:08
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	27 Aug 2020 17:59:21
User entered empty.	Taylor Ladson (b) (4)	27 Aug 2020 17:59:21
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:08
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:10
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:11
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2007'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:17
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:18
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:20
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:59:21

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:44:48
Data point term sent to Coder	System	27 Aug 2020 18:00:45
User entered 'flonase'	Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:19:56
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' answered with 'Med History added.' (Site from DM).	David Diemert (b) (4) (b) (4)	16 Oct 2020 21:11:17
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:15:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:26:23
User entered 'seasonal allergies'	Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 21:14:38
User entered '100' reason for change: New Information	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 21:14:38
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '2'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:59:51
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:33:32
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 21:14:38
User entered 'ug (ug)' reason for change: New Information	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 21:14:38
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'puff (PUFF)'	(b) (4)	
	Taylor Ladson (b) (4)	27 Aug 2020 17:59:51
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Nasal (NASAL)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'un UNK 2010'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered '0'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered empty.	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:26:23
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:59:51

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 14:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 14:43:43
Data point term sent to Coder	System	05 Jan 2021 14:42:57
User entered 'Influenza vaccine'	Erika Faust (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'Flu prevention'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered '0.5'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'mL (mL)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered '23 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered '23 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:17:03
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:41
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
User entered empty.	System	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
User entered empty.	System	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:31:13
User entered empty.	System	05 Jan 2021 14:42:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:37:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:37:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Jan 2021 02:40:52
Data point term sent to Coder	System	14 Jan 2021 17:01:09
User entered 'Motrin'	Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Nephrolithiasis'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '800'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'as needed (PRN)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '10 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
Signature has been broken.	(b) (4) Erika Faust (b) (4)	19 Feb 2021 17:44:55
User entered 'No (N)' reason for change: New Information	(b) (4) Erika Faust (b) (4)	19 Feb 2021 17:44:55
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:44:55
User entered '17 Jan 2021' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:44:55
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	14 Jan 2021 17:00:11
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:20:42
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:52
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
User entered empty.	System	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
User entered empty.	System	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:24
User entered empty.	System	14 Jan 2021 17:00:11

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:18:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:18:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	19 Feb 2021 17:25:02
Data point term sent to Coder	System	18 Feb 2021 15:34:45
User entered 'Tramadol'	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Nephrolithiasis'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'unknown'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Other (OTHER)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Unknown'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'as needed (PRN)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '15 Jan 2021'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '17 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:34:39
User entered '17 Feb 2021'	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:34:30
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:21:42
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
User entered empty.	System	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
User entered empty.	System	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:33:17
User entered empty.	System	18 Feb 2021 15:34:30

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 05:37:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 05:37:29
Data point term sent to Coder	System	23 Mar 2021 18:36:15
Coding entries removed.	David Diemert (b) (4)	23 Mar 2021 18:35:38
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:53:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:53:46
Data point term sent to Coder	System	18 Feb 2021 15:35:46
User entered 'Oxycodone'	Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:41
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:35:38
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 18:35:38
User entered 'NEPHROLITHIASIS' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Nephrolithotomy / Stent Placement'	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '5'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'as needed (PRN)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate..' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:45:21
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate..' answered with 'Indication updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	23 Mar 2021 18:35:50
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate..' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:55:31
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	19 Feb 2021 17:25:02
User entered '10 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	09 Mar 2021 18:56:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Taylor Ladson (b) (4)	09 Mar 2021 18:56:10
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:45:29
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' answered with 'Indication updated.' (Site from DM).	David Diemert (b) (4)	23 Mar 2021 18:36:01
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:55:21
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:54
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	09 Mar 2021 18:56:10
User entered '11 Feb 2021' reason for change: New Information	(b) (4)	
	Taylor Ladson (b) (4)	09 Mar 2021 18:56:10
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	18 Feb 2021 15:35:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User entered empty.	System	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User entered empty.	System	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:24:40
User entered empty.	System	18 Feb 2021 15:35:23

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:25:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:25:26
Data point term sent to Coder Coding entries removed.	System Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:24:22 25 Mar 2021 13:23:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 22:13:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 22:13:50
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	19 Feb 2021 17:25:02
Data point term sent to Coder User entered 'Motrin'	System Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:47 18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:48
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:22
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:22
User entered 'NEPHROLITHIASIS' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered 'Nephrolithotomy / Stent placement'	Caroline Thoreson (b) (4)	18 Feb 2021 15:36:09
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '800'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'as needed (PRN)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '10 Feb 2021'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:45:35
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:45:35
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Feb 2021 15:36:09
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:45:35
User entered '16 Feb 2021' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:45:35
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	18 Feb 2021 15:36:09
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:45
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
User entered empty.	System	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
User entered empty.	System	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:27
User entered empty.	System	18 Feb 2021 15:36:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 13:40:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 13:40:27
Data point term sent to Coder Coding entries removed.	System	25 Mar 2021 13:24:23
	Erika Faust (b) (4)	25 Mar 2021 13:23:38
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 15:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 15:37:52
Data point term sent to Coder User entered 'Tylenol'	System	18 Feb 2021 15:36:48
	Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:55
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:38
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:38
User entered 'NEPHROLITHIASIS' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	25 Mar 2021 13:23:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered 'Nephrolithotomy / Stent placement'	Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '1000'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'as needed (PRN)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '10 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:18:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 15:36:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:25:23
User entered 'Cefazolin'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:01
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:02
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Pre-procedure infection prophylaxis'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:04
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '2'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:05
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'g (g)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:08
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:10
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:12
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:13
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:15
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:17
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:18
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:20
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:21
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:23
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
User entered empty.	System	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
User entered empty.	System	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:26
User entered empty.	System	25 Mar 2021 13:25:09

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:55:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder System		25 Mar 2021 13:27:25
User entered 'Rocuronium'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / Stent Placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '10'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
User entered empty.	System	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
User entered empty.	System	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:29:23
User entered empty.	System	25 Mar 2021 13:26:45

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ETOMIDATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:28:27
User entered 'Etomidate'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / Stent Placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '18'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
User entered empty.	System	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
User entered empty.	System	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:05
User entered empty.	System	25 Mar 2021 13:27:27

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:34:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:28:26
User entered 'Propofol'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / Stent Placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '50'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
User entered empty.	System	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
User entered empty.	System	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:27:39
User entered empty.	System	25 Mar 2021 13:28:14

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:29:28
User entered 'Fentanyl'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / Stent Placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '150'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
User entered empty.	System	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
User entered empty.	System	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:19:25
User entered empty.	System	25 Mar 2021 13:29:02

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:47:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:47:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:30:29
User entered 'Lidocaine'	Erika Faust (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / Stent Placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '100'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
User entered empty.	System	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
User entered empty.	System	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:25
User entered empty.	System	25 Mar 2021 13:29:44

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM, PRODUCTSYNONYM: SUCCINYLCHOLINE [SUXAMETHONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:11:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:11:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder System	System	25 Mar 2021 13:31:31
User entered 'Succinylcholine'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / stent placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '100'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
User entered empty.	System	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
User entered empty.	System	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:34:32
User entered empty.	System	25 Mar 2021 13:30:58

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:40:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:40:15
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:32:32
User entered 'Dexamethasone'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / stent placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '10'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
User entered empty.	System	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
User entered empty.	System	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:14:11
User entered empty.	System	25 Mar 2021 13:31:32

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:23:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:23:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:32:32
User entered 'Ephedrine'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / stent placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '10'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
User entered empty.	System	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
User entered empty.	System	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:18:58
User entered empty.	System	25 Mar 2021 13:32:06

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:02:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:33:33
User entered 'Phenylephrine'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / stent placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '100'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'ug (ug)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
User entered empty.	System	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
User entered empty.	System	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:26:10
User entered empty.	System	25 Mar 2021 13:32:52

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:48:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:48:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:34:33
User entered 'Ondansetron'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Nephrolithotomy / stent placement'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '4'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '09 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
User entered empty.	System	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
User entered empty.	System	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:49
User entered empty.	System	25 Mar 2021 13:33:42

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	System	25 Mar 2021 13:34:33
User entered 'Vitamin D'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Prevention of Vitamin D deficiency'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '1000'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'IU (IU)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once daily (QD)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 13:34:31

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:48:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:48:33
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
Data point term sent to Coder	(b) (4) System	25 Mar 2021 13:35:34
User entered 'Vitamin C'	Erika Faust (b) (4)	25 Mar 2021 13:35:17
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Prevention of Vitamin C deficiency'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered '500'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'once daily (QD)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:50
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 13:35:17

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: GONADOTROPIN RELEASING HORMONE ANALOGUES, PRODUCT: LEUPRORELIN ACETATE, PRODUCTSYNONYM: LUPRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:15:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:15:56
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
Data point term sent to Coder	(b) (4)	22 Apr 2021 19:29:04
User entered 'Lupron'	System	22 Apr 2021 19:29:04
	Hannah Yellin (b) (4)	22 Apr 2021 19:28:20
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Worsening of prostate cancer'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'unk'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Other (OTHER)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'unk'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'once (ONCE)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '04 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:28:20

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 19:30:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:30:01
Data point term sent to Coder	System	22 Apr 2021 19:29:05
User entered 'Norvasc'	Hannah Yellin (b) (4) (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Pancreatitis'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '2.5'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'once daily (QD)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '16 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:11
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:28:50

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 18:01:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:01:03
Data point term sent to Coder	System	23 Apr 2021 18:00:15
User entered 'Pantoprazole'	Hannah Yellin (b) (4) (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Peptic ulcer disease'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '40'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'once daily (QD)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '12 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 17:59:40

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Apr 2021 12:36:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:36:53
Data point term sent to Coder	System	23 Apr 2021 18:00:16
User entered 'Oxycodone'	Hannah Yellin (b) (4) (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Pancreatitis'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '5'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07
	(b) (4)	

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'twice daily (BID)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '09 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '0'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:04:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:00:07

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:04:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:57
User closed query 'Per ETRTR: Per SAE "Acute Pancreatitis" Narrative, please consider 1) checking ConProcedures Action taken within SAE page and 2) adding Procedures details on "ABDOMINAL ULTRASOUND PERFORMED ON 09APR2021 WAS UNREMARKABLE AND CT ABDOMEN ON 08APR2021" within this folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 16:28:28
Query 'Per ETRTR: Per SAE "Acute Pancreatitis" Narrative, please consider 1) checking ConProcedures Action taken within SAE page and 2) adding Procedures details on "ABDOMINAL ULTRASOUND PERFORMED ON 09APR2021 WAS UNREMARKABLE AND CT ABDOMEN ON 08APR2021" within this folder, thanks.' answered with 'Added.' (Site from CRA).	David Diemert (b) (4) (b) (4)	26 Apr 2021 17:57:08
User opened query 'Per ETRTR: Per SAE "Acute Pancreatitis" Narrative, please consider 1) checking ConProcedures Action taken within SAE page and 2) adding Procedures details on "ABDOMINAL ULTRASOUND PERFORMED ON 09APR2021 WAS UNREMARKABLE AND CT ABDOMEN ON 08APR2021" within this folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 19:54:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:41:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	19 Feb 2021 17:25:02
Signature has been broken.	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:24:50
User entered 'Yes (Y)' reason for change: New Information	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:24:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	04 Feb 2021 22:31:33
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	03 Feb 2021 19:10:28

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:26:34
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:46:17
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	19 Feb 2021 17:46:17
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '9 Feb 2021'	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:25:59
	(b) (4)	

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:26:34
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'Nephrolithotomy and Right ureteral stent placement'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:25:59

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:26:34
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	18 Feb 2021 15:26:32
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	18 Feb 2021 15:25:59
User entered 'Adverse Event (AE)'	Caroline Thoreson (b) (4) (b) (4)	18 Feb 2021 15:25:59

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:26:34
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered empty; reason for change Data Entry Error	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:26:32
User entered 'Nephrolithiasis'	(b) (4)	
	Caroline Thoreson (b) (4)	18 Feb 2021 15:25:59
	(b) (4)	

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '12 Apr 2021'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:01:31

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Groin abscess incision and drainage'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:01:31

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'Adverse Event (AE)'	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:01:31

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered empty.	(b) (4) Hannah Yellin (b) (4)	23 Apr 2021 18:01:31

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered '09 Apr 2021'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:16

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Abdominal ultrasound'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:16

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:16

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered empty.	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:16

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered '08 Apr 2021'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:43

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:04:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Abdominal CT'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:43

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:43

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:04:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered empty.	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:54:43

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:04:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered '11 Apr 2021'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:55:04

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:04:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Esophagogastroduodenoscopy'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:55:04

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:04:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:55:04

US3542061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:04:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 18:15:09
User entered empty.	(b) (4) David Diemert (b) (4)	26 Apr 2021 17:55:04

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'USA-US084-2021-MRNA-1273-P301000005'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:29
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:33
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:35
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:44:16
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	10 Mar 2021 17:25:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:45
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:31

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:23:48
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:42
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:43
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:45
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'David'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Diemert'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '2300 Eye Street NW'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:53
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Washington'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '20037'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:29
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'US'	(b) (4) System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Mar 2021 16:01:17
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:15:49
User entered '2'	System	19 Feb 2021 18:15:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered '1'	System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'USA-US084-2021-MRNA-1273-P301000005'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
	(b) (4), (b) (6)	
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:33
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:35
	(b) (4), (b) (6)	
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:44:16
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	10 Mar 2021 17:25:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:45
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:31

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:23:48
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:42
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:43
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:45
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'David'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Diemert'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '2300 Eye Street NW'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:53
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Washington'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '20037'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:29
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'US'	(b) (4) System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Mar 2021 16:01:17
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:15:49
User entered '2'	System	19 Feb 2021 18:15:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered '1'	System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered '18/Feb/2021 16:45'	(b) (4) System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:29
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'USA-US084-2021-MRNA-1273-P301000005'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:29
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:33
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:35
	(b) (4), (b) (6)	
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:44:16
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	10 Mar 2021 17:25:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:45
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:31

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:23:48
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:42
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:43
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:45
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'David'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Diemert'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '2300 Eye Street NW'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:53
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Washington'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '20037'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:29
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'US'	(b) (4) System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Mar 2021 16:01:17
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:15:49
User entered '2'	System	19 Feb 2021 18:15:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered '1'	System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
User entered '19/Feb/2021 13:15'	(b) (4) System	19 Feb 2021 18:15:49

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
User entered 'l'	(b) (4), (b) (6)	19 Feb 2021 18:15:49

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'USA-US084-2021-MRNA-1273-P301000005'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
	(b) (4), (b) (6)	
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:33
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 18:41:08
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 18:28:12
DataPoint Un-verified.	System	23 Mar 2021 18:28:12
Signature has been broken.	System	23 Mar 2021 18:28:12
User entered 'No (N)'	System	23 Mar 2021 18:28:12
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:35
	(b) (4), (b) (6)	
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:44:16
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	10 Mar 2021 17:25:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:45
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:31

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:23:48
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Yes (Y)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:42
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:43
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'No (N)'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:45
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'David'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Diemert'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '2300 Eye Street NW'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:53
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered 'Washington'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 21:45:44
User entered '20037'	System	18 Feb 2021 21:45:20

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 14:40:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:36
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:32
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:15:29
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
User entered 'US'	(b) (4) System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Mar 2021 16:01:17
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:38
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:15:49
User entered '2'	System	19 Feb 2021 18:15:49
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:02
	(b) (4)	
User entered '1'	System	18 Feb 2021 21:45:50

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:31
User entered '09/Mar/2021 08:01'	(b) (4) System	09 Mar 2021 16:01:17

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 15:06:23
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:01:51
User entered 'l'	(b) (4), (b) (6)	09 Mar 2021 16:01:17

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'USA-US084-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'David'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Diemert'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '2300 Eye Street NW'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Washington'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '20037'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'US'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 19:21:26
User entered '3'	System	29 Apr 2021 19:02:51
User entered '2'	System	23 Apr 2021 17:27:34
User entered '1'	System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'USA-US084-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'David'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Diemert'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '2300 Eye Street NW'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Washington'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '20037'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'US'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 19:21:26
User entered '3'	System	29 Apr 2021 19:02:51
User entered '2'	System	23 Apr 2021 17:27:34
User entered '1'	System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered '21/Apr/2021 11:51'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'USA-US084-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'David'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Diemert'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '2300 Eye Street NW'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Washington'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '20037'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'US'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 19:21:26
User entered '3'	System	29 Apr 2021 19:02:51
User entered '2'	System	23 Apr 2021 17:27:34
User entered '1'	System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered '23/Apr/2021 17:27'	(b) (4) System	23 Apr 2021 17:27:34

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:21:31
User signature succeeded.	David Diemert (b) (4)	26 Apr 2021 14:14:31
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 17:27:34

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'USA-US084-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'David'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Diemert'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '2300 Eye Street NW'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Washington'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '20037'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'US'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 19:21:26
User entered '3'	System	29 Apr 2021 19:02:51
User entered '2'	System	23 Apr 2021 17:27:34
User entered '1'	System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:23
User entered '29/Apr/2021 12:02'	(b) (4) System	29 Apr 2021 19:02:51

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:21:31
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:23
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 19:02:51

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'USA-US084-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Yes (Y)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'No (N)'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'David'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Diemert'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '2300 Eye Street NW'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered 'Washington'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:51:44
User entered '20037'	System	21 Apr 2021 15:50:45

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:37
User entered 'US'	(b) (4) System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 19:21:26
User entered '3'	System	29 Apr 2021 19:02:51
User entered '2'	System	23 Apr 2021 17:27:34
User entered '1'	System	21 Apr 2021 15:51:52

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:04:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	02 May 2021 21:15:39
User entered '30/Apr/2021 15:21'	(b) (4) System	30 Apr 2021 19:21:26

US3542061

Folder: SAE USA-US084-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:04:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	02 May 2021 21:15:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:21:31
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 19:21:26