

US3572134 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:16:20

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US3572134

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:31:19

Generated On: 10 Jun 2021 08:16:20

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Participant ID

US3572134

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

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US3572134

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 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) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	ANXIETY
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	DIZZINESS
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)	

US3572134

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	FREQUENT FALLS
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 (6)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	HARD OF HEARING
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 (7)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	OBESITY
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 (8)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN JAN 2004
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 JAN 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	ALCOHOLISM
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) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	FATTY LIVER
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 (11)

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Condition	SEIZURES
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: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:20
Height (xxx.x)	73 in
Weight (xxx.x)	241.4 lb
BMI (xxx.x)	31.91548 kg/m <sup>2</sup>
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) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

28 AUG 2020

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*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) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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**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) 22 Mar 2021 03:34:59

Generated On: 10 Jun 2021 08:16:20

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109673

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) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:30
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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)	28 AUG 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:46
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 13:15 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 13:15

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	12:23 (24 HR)
Collection date and time (derived)	28 AUG 2020 12:23

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:32	28 AUG 2020 12:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 28 AUG 2020 14:01

PC Open Date & Time 28 AUG 2020 13:35

PC Close Date & Time 28 AUG 2020 16:05

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**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

97.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	28 AUG 2020 20:43
PC Open Date & Time	28 AUG 2020 17:00
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 22:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 14:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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**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

97.5 °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 13:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**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

97.9 °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

02 SEP 2020 19:24

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:02

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 14:02

PC Open Date & Time

28 AUG 2020 13:35

PC Close Date & Time

28 AUG 2020 16:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**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

28 AUG 2020 20:43

PC Open Date & Time

28 AUG 2020 17:00

PC Close Date & Time

29 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 22:44

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 14:50

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:24

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**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 ☐

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:03
PC Open Date & Time	28 AUG 2020 13:35
PC Close Date & Time	28 AUG 2020 16:05

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**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 ☐

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:45
PC Open Date & Time	28 AUG 2020 17:00
PC Close Date & Time	29 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2944

EAB) (1725)



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:44
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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 2944

EAB) (1725)

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 14:52
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**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

EAB) (1725)

55 of 2944

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:23
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

57 of 2944

EAB) (1725)

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 13:20
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2944

EAB) (1725)



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:26
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2944

EAB) (1725)

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**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

04 SEP 2020 12:28

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

**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

05 SEP 2020 12:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

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**TIMEPOINT**

DAY 10

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

---

PC Open Date & Time

06 SEP 2020 12:00

---

PC Close Date & Time

07 SEP 2020 11:59

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US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 11

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

07 SEP 2020 17:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 12

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

08 SEP 2020 16:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 12:29
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 12:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 17:48
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 16:32
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3572134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3572134

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:10
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 11:02

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

What was the frequency of the study treatment dosing? ONCE

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



US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	29 SEP 2020 10:46

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:12	29 SEP 2020 10:12
Nasopharyngeal Swab 2	No		

US3572134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 11:35

PC Open Date & Time

29 SEP 2020 11:22

PC Close Date & Time

29 SEP 2020 13:52

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	29 SEP 2020 23:08
PC Open Date & Time	29 SEP 2020 14:47
PC Close Date & Time	30 SEP 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 04:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 23:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**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

02 OCT 2020 12:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 17:39

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 17:24

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**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

29 SEP 2020 11:36

PC Open Date & Time

29 SEP 2020 11:22

PC Close Date & Time

29 SEP 2020 13:52

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**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

29 SEP 2020 23:09

PC Open Date & Time

29 SEP 2020 14:47

PC Close Date & Time

30 SEP 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**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

01 OCT 2020 04:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**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

01 OCT 2020 23:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**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

02 OCT 2020 12:50

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**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

03 OCT 2020 17:39

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**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

04 OCT 2020 17:25

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**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 ☐

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 11:37
PC Open Date & Time	29 SEP 2020 11:22
PC Close Date & Time	29 SEP 2020 13:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**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 ☐

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 23:10
PC Open Date & Time	29 SEP 2020 14:47
PC Close Date & Time	30 SEP 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**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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US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 04:15
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

109 of 2944

EAB) (1725)

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 23:29
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**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

EAB) (1725)

111 of 2944

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:51
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 17:41
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 17:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 06 OCT 2020 12:47

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 8

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

06 OCT 2020 12:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 06 OCT 2020 12:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:16:20

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**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 06 OCT 2020 12:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**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 06 OCT 2020 12:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

**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

07 OCT 2020 15:28

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 10

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

08 OCT 2020 16:18

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 11

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

10 OCT 2020 06:24

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 12

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

11 OCT 2020 01:45

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(13)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 13

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 11 OCT 2020 18:47

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(14)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 14

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 12 OCT 2020 15:39

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(15)

Generated On: 10 Jun 2021 08:16:20

---

**TIMEPOINT**

DAY 15

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

---

PC Open Date & Time

13 OCT 2020 12:00

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PC Close Date & Time

14 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(16)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 16

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 14 OCT 2020 16:50

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(17)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 17

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

15 OCT 2020 14:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(18)

Generated On: 10 Jun 2021 08:16:20

---

**TIMEPOINT**

DAY 18

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

---

PC Open Date & Time

16 OCT 2020 12:00

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PC Close Date & Time

17 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(19)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 19

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

18 OCT 2020 11:33

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(20)

Generated On: 10 Jun 2021 08:16:20

---

**TIMEPOINT**

DAY 20

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

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PC Open Date & Time

18 OCT 2020 12:00

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PC Close Date & Time

19 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(21)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 21

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 19 OCT 2020 16:20

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(22)

Generated On: 10 Jun 2021 08:16:20

---

**TIMEPOINT**

DAY 22

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

---

PC Open Date & Time

20 OCT 2020 12:00

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PC Close Date & Time

21 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(23)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 23

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

21 OCT 2020 14:09

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(24)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 24

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

22 OCT 2020 13:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(25)

Generated On: 10 Jun 2021 08:16:20

---

**TIMEPOINT**

DAY 25

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

24 OCT 2020 03:43

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PC Open Date & Time

23 OCT 2020 12:00

---

PC Close Date & Time

24 OCT 2020 11:59

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US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(26)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 26

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 24 OCT 2020 12:00

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(27)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 27

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 25 OCT 2020 22:01

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(28)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 28

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

26 OCT 2020 13:00

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(29)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 29

Select one response below to indicate the level of your

None ☒

**NAUSEA/VOMITING**

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

27 OCT 2020 18:35

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 12:46
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 16:17
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 06:23
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 01:44
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 18:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 OCT 2020 15:39
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 16
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 16:50
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 17

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

No ☒

Yes ☐

PC Time stamp

15 OCT 2020 14:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 18
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 19
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 11:34
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 20
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 21
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	19 OCT 2020 16:20
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 22
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 23
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 14:09
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 24
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	22 OCT 2020 13:12
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT

DAY 25

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

No ☐

Yes ☒

PC Time stamp

24 OCT 2020 03:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 26
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 12:00
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 27
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 22:01
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 28
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 13:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 29
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 18:35
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:21
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	129 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

28 OCT 2020 10:30

US3572134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:13:01

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 OCT 2020 10:14:12
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	06 NOV 2020 11:41:19
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 NOV 2020 15:14:10
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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06 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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10 DEC 2020 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2020 23:59



US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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	28 DEC 2020 16:05:49
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	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	03 JAN 2021 16:52:41
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 12:23:15

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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

18 JAN 2021 07:53:37

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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

26 JAN 2021 07:13:33

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 JAN 2021 07:09:53
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59



US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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

14 FEB 2021 11:06:21

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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28 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	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	11 MAR 2021 13:56:07
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59



US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	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	15 MAR 2021 06:17:39
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 MAR 2021 08:25:22
Patient Cloud Open Date & Time	21 MAR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	205 of 2944

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 MAR 2021 02:12:08
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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

04 APR 2021 00:01:43

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 APR 2021 03:18:03
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 APR 2021 12:51:50
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 21:54:16

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59



US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAY 2021 13:21:44
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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 <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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 NOV 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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12 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 DEC 2021 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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°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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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 <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"/>

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**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 ☐

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3572134

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:16:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		11 MAR 2021 13:55:16

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:15:24

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:15:24

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3572134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3572134**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

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 \_\_\_\_\_

US3572134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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)	



US3572134

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

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.*

US3572134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<input type="text"/>
Collection time ( <i>00:00-23:59</i> )	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3572134

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:08:04

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:08:04

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:08:04

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3572134**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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*

**US3572134**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572134

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:16:20

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"/>



**US3572134**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 08:16:20**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3572134

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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

---

Visit date (dd MMM yyyy)	09 FEB 2021
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---

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

---

Folder OID	UNBLND_DECIDE
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US3572134

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Date of updated informed consent ( <i>dd MMM yyyy</i> )	09 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	09 FEB 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

US3572134

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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

US3572134

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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)	12 FEB 2021
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 16:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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)	12 FEB 2021
Time of assessment (00:00-23:59)	18:10 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 18:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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.*

US3572134

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 17:40 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 17:40

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



US3572134

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 FEB 2021
Collection time (00:00-23:59)	15:11 (24 HR)
Collection date and time (derived)	09 FEB 2021 15:11

US3572134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 FEB 2021
Collection time (00:00 - 23:59)	15:09
Collection Date and Time (derived)	09 FEB 2021 15:09

US3572134

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	OLD29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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)	17 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 14:15
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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)	17 MAR 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 15:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



US3572134

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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.*

US3572134

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

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) 17 MAR 2021

What was the treatment time? (00:00-23:59) 15:05 (24 HR)

Treatment Date and Time (derived) 17 MAR 2021 15:05

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

US3572134

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572134

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:31:22

Generated On: 10 Jun 2021 08:16:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:40:33

Generated On: 10 Jun 2021 08:16:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:40:33

Generated On: 10 Jun 2021 08:16:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 APR 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572134

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:40:33

Generated On: 10 Jun 2021 08:16:20

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.*



US3572134

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:40:33

Generated On: 10 Jun 2021 08:16:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

14:52 (24 HR)

Collection date and time (derived)

19 APR 2021 14:52

US3572134

Folder: Unscheduled 22 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 28 Apr 2021 10:08:04

Generated On: 10 Jun 2021 08:16:20

Visit Date	22 OCT 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3572134

Folder: Unscheduled 22 Oct 2020

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:08:04

Generated On: 10 Jun 2021 08:16:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3572134

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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)	17 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)	17 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	

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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)	_____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	VOMITING
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)	17 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)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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:	
<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 (5)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	DIARRHEA
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)	17 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)	17 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 (5)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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:	
<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 (6)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 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)	17 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 (6)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	DIARRHEA
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)	2 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)	5 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) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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THE SUBJECT REPORTED THE  
DIARRHEA STARTED AFTER  
DOSE 2 (UNDER PROTOCOL  
AMENDMENT 5) THE SUBJECT  
HAD VISIT DAY 1 OL  
(AMENDMENT 6) YESTERDAY,  
HE DISCLOSED HE HAS A  
HISTORY OF GASTRIC BYPASS,  
THIS WAS NOT PREVIOUSLY  
REPORTED. SITE MADE CRA  
AWARE

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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) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	USA-US091-2020-MRNA-1273-P30 1000003
Adverse event	FALL
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 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	9 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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MEDICAL RECORDS WERE  
RECEIVED FOR SUBJECT'S  
HOSPITALIZATION. RECORDS  
INDICATE SUBJECT HAS A  
HISTORY OF ALCOHOLISM AND  
FATTY LIVER. RECORDS HAVE  
NO INDICATION THAT  
SUBJECTS EVENT HAS ANY  
CAUSAL RELATIONSHIP TO IP.

---

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 (10)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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)	5 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 FEB 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 (10)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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 (11)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	USA-US091-2020-MRNA-1273-P30 1000003
Adverse event	MACROCYTIC ANEMIA
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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	DIARRHEA
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)	17 MAR 2021
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	17 MAR 2021 00:00
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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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



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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

AEID	
Adverse event	SPINAL PAIN
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)	1 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (13)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT PREVIOUSLY HAD NECK SURGERY. PCP THINKS THIS IS RELATED, PER SUBJECT
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)	

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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)	29 SEP 2020
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	29 SEP 2020 12:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 OCT 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	26 OCT 2020 12:00
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	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 29 Apr 2021 15:47:36

Generated On: 10 Jun 2021 08:16:20

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)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

---

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

Yes ☒

No ☐

---

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

---

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication EXCEDRIN - ACETAMINOPHEN,  
ASPIRIN, CAFFEINE

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

	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)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN DUE TO FALL

Dose per administration 1,000

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

Q4H-INT, PRN

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication PAIN DUE TO FALL

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q4H-INT, PRN

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 (3)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication XANAX

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

	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 2019	
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"/>

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication KEPPRA

Prophylaxis Yes ☐  
No ☒

Indication SEIZURES

Dose per administration 1500

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 (5)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 600

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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US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

	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 2017	
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"/>

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:31:21

Generated On: 10 Jun 2021 08:16:20

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 11 Apr 2021 07:08:39

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 NOV 2020	CT (COMPUTED TOMOGRAPHY) ABDOMEN PELVIS W	Adverse Event	
08 NOV 2020	CT HEAD OR BRAIN WO	Adverse Event	
08 NOV 2020	XR HUMERUS MIN 2 V RIGHT DR, XR FOREARM 2 V RIGHT DR, XR SHOULDER COMPLETE MIN 2 V RIGHT DR	Adverse Event	
09 NOV 2020	NI ECHO TRANSTHORACIC ECHOCARDIOGRAM (TTE) 2D	Adverse Event	
09 NOV 2020	NM MYOCARDIAL PERFUSION STRESS MULTI	Medical History	
09 NOV 2020	ABDOMEN ULTRASOUND	Medical History	

US3572134

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:20

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

US3572134

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:20

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 ☐

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	10/NOV/2020 21:14
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

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:30
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



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	18/NOV/2020 11:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:27
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

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/FEB/2021 10:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/FEB/2021 15:07
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

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:55
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

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	27/APR/2021 10:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:16:20

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/APR/2021 14:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3572134 (Prod: Laguna Clinical Research Associates)

**US3572134**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:16:20**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'US3572134'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:59:18

US3572134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:29:06

US3572134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:59:19

US3572134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:29:06

**US3572134**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'SCRN'	System	28 Aug 2020 18:29:06

US3572134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered (b) (6) 1972'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:59:20

US3572134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '48'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56



**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'YEARS'	System	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '48'	System	28 Aug 2020 18:35:36

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Male (M)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4) System	28 Aug 2020 18:33:12
User entered '1' reason for change: Data Entry Error	Alisha Lutat (b) (4)	28 Aug 2020 18:33:12
User opened query 'Race has not been provided. Please correct.' (Site from System).	(b) (4) System	28 Aug 2020 18:32:56
User entered '0'	Alisha Lutat (b) (4)	28 Aug 2020 18:32:56
	(b) (4)	

US3572134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56



**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

**US3572134**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:16:20**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

**US3572134**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Aug 2020'	System	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2020'	System	28 Aug 2020 18:35:36



**US3572134**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:16:20**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Amendment 3 (3)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

**US3572134**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

**US3572134**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:16:20**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:59:19

US3572134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'l'	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:44



US3572134

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:16:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:26

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
Data point term sent to Coder	System	06 Nov 2020 00:32:49
User entered 'Insomnia'	Alisha Lutat (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Un UNK 2017'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Jan 2017'	System	06 Nov 2020 00:32:21



**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2017'	System	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	06 Nov 2020 00:32:21

**US3572134**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
Data point term sent to Coder	System	06 Nov 2020 00:33:55
User entered 'Anxiety'	Alisha Lutat (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Un Aug 2019'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59



**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Aug 2019'	System	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2019'	System	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	06 Nov 2020 00:32:59

**US3572134**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
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)	05 Feb 2021 17:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 17:57:46
Data point term sent to Coder	System	05 Feb 2021 17:56:38
User entered 'DIZZINESS'	(b) (4), (b) (6)	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:56:26



**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:56:26

**US3572134**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:56:26

US3572134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 17:59:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 17:59:01
Data point term sent to Coder	System	05 Feb 2021 17:58:40
User entered 'frequent falls'	(b) (4), (b) (6)	05 Feb 2021 17:58:18



**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:18

**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:18



**US3572134**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:18

US3572134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Hard of hearing - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 18:00:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 18:00:52
Data point term sent to Coder	System	05 Feb 2021 17:59:41
User entered 'hard of hearing'	(b) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:53



**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:53

US3572134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:53

**US3572134**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:58:53

US3572134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 18:00:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 18:00:52
Data point term sent to Coder	System	05 Feb 2021 17:59:41
User entered 'obesity'	(b) (4), (b) (6)	05 Feb 2021 17:59:12

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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:59:12

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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:59:12



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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:59:12

**US3572134**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	05 Feb 2021 17:59:12

US3572134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 08:22:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 08:22:08
Data point term sent to Coder	System	26 Feb 2021 08:20:58
User entered 'Gastric bypass'	(b) (4), (b) (6)	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'UN Jan 2004' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 06:05:52
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 08:20:26

US3572134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User closed query 'Per CDM: Please consider to update the Start date if known as procedures/surgeries typically have the same start and stop date. Please review and update the start date, else clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	17 Mar 2021 06:27:06
Query 'Per CDM: Please consider to update the Start date if known as procedures/surgeries typically have the same start and stop date. Please review and update the start date, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:05:59
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 06:05:52
User opened query 'Per CDM: Please consider to update the Start date if known as procedures/surgeries typically have the same start and stop date. Please review and update the start date, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:11:33
User entered '1'	(b) (4), (b) (6)	26 Feb 2021 08:20:26



US3572134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User closed query 'Per DM CLR: Ongoing is marked for a surgical/medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:02:52
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	12 Mar 2021 16:32:09
Query 'Per DM CLR: Ongoing is marked for a surgical/medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:31:45
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	12 Mar 2021 16:31:04
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Mar 2021 16:31:04
User opened query 'Per DM CLR: Ongoing is marked for a surgical/medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:56:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 08:20:26

US3572134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 17:50:14
User entered 'UN Jan 2004' reason for change: Data Entry Error	System	12 Mar 2021 17:50:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Maria Candelario (b) (4)	12 Mar 2021 16:32:09
User entered 'UN UNK unk' (non-conformant).	(b) (4)	12 Mar 2021 16:32:09
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Jan 2004'	System	16 Mar 2021 06:05:52
User entered empty.	System	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2004'	System	16 Mar 2021 06:05:52
User entered empty.	System	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Jan 2004'	System	12 Mar 2021 17:50:14
User entered empty.	System	26 Feb 2021 08:20:26

**US3572134**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2004'	System	12 Mar 2021 17:50:14
User entered empty.	System	26 Feb 2021 08:20:26

US3572134

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcoholism - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 14:17:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 14:17:52
Data point term sent to Coder	System	16 Mar 2021 14:17:40
User entered 'Alcoholism'	(b) (4), (b) (6)	16 Mar 2021 14:17:24



**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:17:24

**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:17:24



**US3572134**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:17:24

US3572134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 14:19:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 14:19:51
Data point term sent to Coder	System	16 Mar 2021 14:19:42
User entered 'Fatty liver'	(b) (4), (b) (6)	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'l'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:19:13

US3572134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:19:13



**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:19:13

**US3572134**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	16 Mar 2021 14:19:13

US3572134

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:03:45
Data point term sent to Coder	System	17 Mar 2021 16:03:26
User entered 'Seizures'	(b) (4), (b) (6)	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 16:02:43



**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'Jan 2015'	System	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '2015'	System	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	17 Mar 2021 16:02:43

**US3572134**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered empty.	System	17 Mar 2021 16:02:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '12:20'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43



**US3572134**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '28 Aug 2020 12:20'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '73' in	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:49:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '241.4' lb	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:49:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered '31.91548'	System	06 Nov 2020 00:49:43
DataPoint set to visible.	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'kg/m2'	System	06 Nov 2020 00:49:43
DataPoint set to visible.	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43



**US3572134**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

**US3572134**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'bpm'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'breaths/min'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

**US3572134**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'mmHg'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

**US3572134**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User entered 'mmHg'	System	06 Nov 2020 00:49:43



US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39

US3572134

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3572134

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04



US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

**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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered 'I'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

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 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04



US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:48:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:59
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 10:20:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Data updated ' (Site from DM).	Maria Candelario (b) (4) (b) (4)	08 Dec 2020 23:49:14
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:17:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'VISIT1'	System	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:39:49

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '109673'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:39:49

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:39:49



US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete this section of the form.' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:03:31
User entered 'No (N)'	Alisha Lutat (b) (4)	06 Nov 2020 00:51:32
	(b) (4)	
	Alisha Lutat (b) (4)	06 Nov 2020 00:51:23
	(b) (4)	
User opened query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 12:19:40
	(6)	

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:16:20**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	06 Nov 2020 00:51:23
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:28:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:28:57

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41



US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '12:30'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Aug 2020 12:30'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '97.3' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41



US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '93'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'bpm'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'breaths/min'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '153'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	06 Nov 2020 00:58:41



US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '102'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	06 Nov 2020 00:58:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Nov 2020 00:58:57
User entered '13:46' reason for change: Data Entry Error	Alisha Lutat (b) (4)	06 Nov 2020 00:58:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	06 Nov 2020 00:58:41
User entered empty.	Alisha Lutat (b) (4)	06 Nov 2020 00:58:41



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Aug 2020 13:46'	System	06 Nov 2020 00:58:57
User entered empty.	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '97.7' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '84'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'bpm'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'breaths/min'	System	06 Nov 2020 00:58:41



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '136'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '93'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:05

US3572134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:05

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 28Aug2020, however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4) (u) (4), (b) (6)	29 Jan 2021 05:45:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 28Aug2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:45:57
Query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 28Aug2020, however the same is missing in EDC. Please add or clarify' answered with 'VID1 immuno added in EDC' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:32:34
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 28Aug2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'VID1 swab sample collected on 28Aug2020 added to EDC' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:32:10
User opened query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 28Aug2020, however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:15:29
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28Aug2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:11:11
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 18:36:26

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '13:15'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Aug 2020 13:15'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'ONCE'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 18:36:26



US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '12:23'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Aug 2020 12:23'	System	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '12:32'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21



**US3572134**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Aug 2020 12:32'	System	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered empty.	System	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	11 Sep 2020 17:40:03

**US3572134**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'I'	System	11 Sep 2020 17:40:03

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:00:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered 'Yes (Y)'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:00:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered '97.7'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered 'No (N)'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered '28 Aug 2020 14:01'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:42:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered 'Yes (Y)'	System	29 Aug 2020 01:43:15



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:42:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered '97.7'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered 'No (N)'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered '28 Aug 2020 20:43'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:42:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered 'Yes (Y)'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:42:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d' User entered '97.7'	System	30 Aug 2020 03:43:10
	System	30 Aug 2020 03:43:10



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered 'No (N)'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered '29 Aug 2020 22:43'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:48:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered 'Yes (Y)'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:48:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered '97.7'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:49:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered 'No (N)'	System	30 Aug 2020 19:49:40



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:49:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered '30 Aug 2020 14:49'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:21:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-cb413d37f832'	System	31 Aug 2020 17:26:04
User entered 'Yes (Y)'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-cb413d37f832'	System	31 Aug 2020 17:26:04
User entered '97.0'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-cb413d37f832'	System	31 Aug 2020 17:26:04
User entered 'No (N)'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:14', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-eb413d37f832'	System	31 Aug 2020 17:26:04
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 17:26:04



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:18:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered 'Yes (Y)'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered '97.5'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered 'No (N)'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered '01 Sep 2020 13:19'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:23:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered 'Yes (Y)'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:23:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered '97.9'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered 'No (N)'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered '02 Sep 2020 19:24'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered 'Yes (Y)'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered '97.3'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered 'No (N)'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered '03 Sep 2020 14:02'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'None (1)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'No (N)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'No (N)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'None (1)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered '28 Aug 2020 14:02'	System	28 Aug 2020 19:02:32

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'None (1)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'No (N)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'No (N)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'None (1)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered '28 Aug 2020 20:43'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'No (N)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'No (N)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'None (1)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered '29 Aug 2020 22:44'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'None (1)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'No (N)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'No (N)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'None (1)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered '30 Aug 2020 14:50'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'None (1)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'No (N)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'No (N)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'None (1)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'None (1)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'No (N)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'No (N)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'None (1)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered '01 Sep 2020 13:19'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'None (1)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'No (N)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'No (N)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'None (1)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered '02 Sep 2020 19:24'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'None (1)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'No (N)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'No (N)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'None (1)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'No (N)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered '28 Aug 2020 14:03'	System	28 Aug 2020 19:03:37



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'No (N)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:45:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered '28 Aug 2020 20:45'	System	29 Aug 2020 01:45:06

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'No (N)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered '29 Aug 2020 22:44'	System	30 Aug 2020 03:44:54

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:52:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'No (N)'	System	30 Aug 2020 19:52:18



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:52:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered '30 Aug 2020 14:52'	System	30 Aug 2020 19:52:18

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'No (N)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered '31 Aug 2020 12:23'	System	31 Aug 2020 17:26:46

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'No interference with activity (1)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'No (N)'	System	01 Sep 2020 18:20:56

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered '01 Sep 2020 13:20'	System	01 Sep 2020 18:20:56

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26



**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'No (N)'	System	03 Sep 2020 00:26:29

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered '02 Sep 2020 19:26'	System	03 Sep 2020 00:26:29

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:14', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40



US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'No (N)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:59
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	03 Sep 2020 00:26:29
User entered 'Day 8'	System	03 Sep 2020 00:26:29



US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '32c119a9-18ad-4282-b7e4-3a1a40b06a71'	System	04 Sep 2020 17:28:48
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Sep 2020 17:28:48

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '32c119a9-18ad-4282-b7e4-3a1a40b06a71'	System	04 Sep 2020 17:28:48
User entered '04 Sep 2020 12:28'	System	04 Sep 2020 17:28:48

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:26:29

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	03 Sep 2020 19:03:40
User entered 'Day 9'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:45:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd746701-bc0c-4e27-b6b6-b62398ccbeed'	System	05 Sep 2020 17:46:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 17:46:03

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd746701-bc0c-4e27-b6b6-b62398ccbeed'	System	05 Sep 2020 17:46:03
User entered '05 Sep 2020 12:46'	System	05 Sep 2020 17:46:03

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:40



**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Sep 2020 17:28:48
User entered 'Day 10'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:28:48

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	05 Sep 2020 17:46:03
User entered 'Day 11'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8144d87b-dd7a-443f-aedf-89474a29eaa1'	System	07 Sep 2020 22:48:14
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Sep 2020 22:48:14



**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8144d87b-dd7a-443f-aedf-89474a29eaal'	System	07 Sep 2020 22:48:14
User entered '07 Sep 2020 17:48'	System	07 Sep 2020 22:48:14

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	07 Sep 2020 22:48:14
User entered 'Day 12'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ffd060a8-6647-4f69-9819-bdd722cb68d0'	System	08 Sep 2020 21:32:42
User entered 'None (0)'	System	08 Sep 2020 21:32:42

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ffd060a8-6647-4f69-9819-bdd722cb68d0'	System	08 Sep 2020 21:32:42
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 21:32:42

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:48:14

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:48:14



US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	03 Sep 2020 00:26:29
User entered 'Day 8'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4af29d69-d325-461c-812e-d6febabee6a1'	System	04 Sep 2020 17:29:09
User entered 'No (N)'	System	04 Sep 2020 17:29:09

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:29:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4af29d69-d325-461c-812e-d6febabee6a1'	System	04 Sep 2020 17:29:09
User entered '04 Sep 2020 12:29'	System	04 Sep 2020 17:29:09

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	03 Sep 2020 19:03:40
User entered 'Day 9'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a95d6518-2791-464b-8fbc-3ae4882bb092'	System	05 Sep 2020 17:46:12
User entered 'No (N)'	System	05 Sep 2020 17:46:12

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a95d6518-2791-464b-8fbc-3ae4882bb092'	System	05 Sep 2020 17:46:12
User entered '05 Sep 2020 12:46'	System	05 Sep 2020 17:46:12



US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Sep 2020 17:28:48
User entered 'Day 10'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

**US3572134**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	05 Sep 2020 17:46:03
User entered 'Day 11'	System	05 Sep 2020 17:46:03



US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b6f64581-4f0c-4d77-8117-0ecd573262aa'	System	07 Sep 2020 22:48:31
User entered 'No (N)'	System	07 Sep 2020 22:48:31

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b6f64581-4f0c-4d77-8117-0ecd573262aa'	System	07 Sep 2020 22:48:31
User entered '07 Sep 2020 17:48'	System	07 Sep 2020 22:48:31

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	07 Sep 2020 22:48:14
User entered 'Day 12'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0177547f-8f6c-4dc0-8a66-af33fcc3f762'	System	08 Sep 2020 21:32:53
User entered 'No (N)'	System	08 Sep 2020 21:32:53

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0177547f-8f6c-4dc0-8a66-af33fcc3f762'	System	08 Sep 2020 21:32:53
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 21:32:53

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:48:14



US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:48:14

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 17:09:58

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '4 Sep 2020'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 17:09:58

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 17:09:58

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 17:09:58

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	11 Sep 2020 17:40:14

**US3572134**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'I'	System	11 Sep 2020 17:40:14

**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	11 Sep 2020 18:02:46



**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '11 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jasmine Ali (b) (4)	11 Sep 2020 18:02:46

**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	11 Sep 2020 18:02:51

**US3572134**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'l'	System	11 Sep 2020 18:02:51

**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:35:56

**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '18 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:35:56

**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:35:56



**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:35:56

**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:36:01

**US3572134**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'I'	System	18 Sep 2020 21:36:01

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:26:49

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:26:49

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Clinic (Clinic)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:26:49

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'VISIT2'	System	30 Sep 2020 12:26:49

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Pre-Dose (PREDOSE)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53



US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '10:10'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '29 Sep 2020 10:10'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '97.7' F	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Other (Other)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Temporal'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '102'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53



US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'bpm'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '20'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'breaths/min'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '134'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '91'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Post-Dose (POSTDOSE)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53



US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Per CDM: The treatment time on the Exposure CRF is 11:02 and the Vital Signs Post Dose Time of Assessment is 11:27 which has 25 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 11:02 and the Vital Signs Post Dose Time of Assessment is 11:27 which has 25 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' answered with 'corrected to time in source' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Jan 2021 06:26:57
User entered '11:32' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 00:34:38
User opened query 'Per CDM: The treatment time on the Exposure CRF is 11:02 and the Vital Signs Post Dose Time of Assessment is 11:27 which has 25 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 00:34:27
User entered '11:27'	(b) (4), (b) (6)	12 Nov 2020 06:38:52
	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '29 Sep 2020 11:32'	System	06 Jan 2021 00:34:27
User entered '29 Sep 2020 11:27'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '98.1' F	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Other (Other)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Temporal'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '99'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53



US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'bpm'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '18'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'breaths/min'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '141'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '94'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:09



**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:16:20**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:09

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '11:02'	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '29 Sep 2020 11:02'	System	29 Sep 2020 16:03:42



US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'ONCE'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '10:46'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '29 Sep 2020 10:46'	System	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '29 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52



US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:30:52

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '10:12'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:30:52

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '29 Sep 2020 10:12'	System	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'No (N)'	(b) (4) Brett Potthoff (b) (4)	30 Sep 2020 12:30:52

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered empty.	System	30 Sep 2020 12:30:52



US3572134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:58

**US3572134**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'I'	System	30 Sep 2020 12:30:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered 'Yes (Y)'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered '98.1'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered 'No (N)'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered '29 Sep 2020 11:35'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered 'Yes (Y)'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered '98.2'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered 'No (N)'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered '29 Sep 2020 23:08'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered 'Yes (Y)'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b' User entered '98.2'	System	01 Oct 2020 09:13:46
	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered 'No (N)'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered '01 Oct 2020 04:13'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered 'Yes (Y)'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered '98.4'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered 'No (N)'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered '01 Oct 2020 23:28'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered 'Yes (Y)'	System	02 Oct 2020 17:49:45



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered '98.3'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered 'No (N)'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered '02 Oct 2020 12:49'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:38:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered 'Yes (Y)'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered '98.5'	System	03 Oct 2020 22:39:13



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered 'No (N)'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered '03 Oct 2020 17:39'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:23:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered 'Yes (Y)'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered '97.2'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered 'No (N)'	System	04 Oct 2020 22:24:16



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered '04 Oct 2020 17:24'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19



US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'None (1)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'No (N)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'No (N)'	System	29 Sep 2020 16:36:38



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'None (1)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered '29 Sep 2020 11:36'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'None (1)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'No (N)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'No (N)'	System	30 Sep 2020 04:09:29



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'None (1)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered '29 Sep 2020 23:09'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'None (1)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'No (N)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'No (N)'	System	01 Oct 2020 09:14:16



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'None (1)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered '01 Oct 2020 04:14'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'None (1)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'No (N)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'No (N)'	System	02 Oct 2020 04:28:31



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'None (1)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered '01 Oct 2020 23:28'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'None (1)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'No (N)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'No (N)'	System	02 Oct 2020 17:50:16



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'None (1)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered '02 Oct 2020 12:50'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcfe567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'None (1)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcf567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'No (N)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcf567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'No (N)'	System	03 Oct 2020 22:39:50



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcfe567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'None (1)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcf567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered '03 Oct 2020 17:39'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'None (1)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'No (N)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbae3ef5'	System	04 Oct 2020 22:25:04
User entered 'No (N)'	System	04 Oct 2020 22:25:04



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'None (1)'	System	04 Oct 2020 22:25:04

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered '04 Oct 2020 17:25'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14



US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No (N)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered '29 Sep 2020 11:37'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'None (0)'	System	30 Sep 2020 04:10:34



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No (N)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered '29 Sep 2020 23:10'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'No (N)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:15:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered '01 Oct 2020 04:15'	System	01 Oct 2020 09:15:08

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'No (N)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered '01 Oct 2020 23:29'	System	02 Oct 2020 04:29:19



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Oct 2020 17:51:07



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:51:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'No (N)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:51:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered '02 Oct 2020 12:51'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'None (0)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No (N)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:41:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered '03 Oct 2020 17:41'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'None (0)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No (N)'	System	04 Oct 2020 22:26:01



US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:26:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered '04 Oct 2020 17:26'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:16:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:16:20**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cd3aced5-8172-4164-a39a-255a14633482'	System	06 Oct 2020 17:47:35
User entered 'None (0)'	System	06 Oct 2020 17:47:35



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cd3aced5-8172-4164-a39a-255a14633482'	System	06 Oct 2020 17:47:35
User entered '06 Oct 2020 12:47'	System	06 Oct 2020 17:47:35

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '01d3de56-2296-4337-bfe1-e8ac9b7ed577'	System	06 Oct 2020 17:47:18
User entered 'None (0)'	System	06 Oct 2020 17:47:18

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '01d3de56-2296-4337-bfe1-e8ac9b7ed577'	System	06 Oct 2020 17:47:18
User entered '06 Oct 2020 12:47'	System	06 Oct 2020 17:47:18

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '94b93e8e-6353-46eb-93fb-a59b14ed4403'	System	06 Oct 2020 17:46:55
User entered 'None (0)'	System	06 Oct 2020 17:46:55

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '94b93e8e-6353-46eb-93fb-a59b14ed4403'	System	06 Oct 2020 17:46:55
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:55

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'de791a24-2177-4ab6-8331-8f70d163c8b5'	System	06 Oct 2020 17:46:40
User entered 'None (0)'	System	06 Oct 2020 17:46:40

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'de791a24-2177-4ab6-8331-8f70d163c8b5'	System	06 Oct 2020 17:46:40
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:40



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '55a7ccfd-afd5-4420-9fee-745003e63a06'	System	06 Oct 2020 17:46:31
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '55a7ccfd-afd5-4420-9fee-745003e63a06'	System	06 Oct 2020 17:46:31
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 9'	System	06 Oct 2020 17:46:31



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-07T15:28:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7a8decd2-5b99-4c34-9acb-11246eaf8ce6'	System	07 Oct 2020 20:28:09
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-07T15:28:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7a8decd2-5b99-4c34-9acb-11246eaf8ce6'	System	07 Oct 2020 20:28:09
User entered '07 Oct 2020 15:28'	System	07 Oct 2020 20:28:09

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 10'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:18:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '3791496a-966e-4c9e-a9b0-36ee66c28781'	System	08 Oct 2020 21:18:12
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:18:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '3791496a-966e-4c9e-a9b0-36ee66c28781'	System	08 Oct 2020 21:18:12
User entered '08 Oct 2020 16:18'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:46:31



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	07 Oct 2020 20:28:09
User entered 'Day 11'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c69be7-1c13-4b9a-b651-1c66c4bc3ec9'	System	10 Oct 2020 11:24:11
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:24:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c69be7-1c13-4b9a-b651-1c66c4bc3ec9'	System	10 Oct 2020 11:24:11
User entered '10 Oct 2020 06:24'	System	10 Oct 2020 11:24:11

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:28:09

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:28:09

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	08 Oct 2020 21:18:12
User entered 'Day 12'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:45:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1934476d-9ed6-4a8c-887c-4f9ced427913'	System	11 Oct 2020 06:45:15
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Oct 2020 06:45:15



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:45:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1934476d-9ed6-4a8c-887c-4f9ced427913'	System	11 Oct 2020 06:45:15
User entered '11 Oct 2020 01:45'	System	11 Oct 2020 06:45:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:18:12

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:18:12

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(13)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	10 Oct 2020 11:24:11
User entered 'Day 13'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(13)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b59ddc09-caa4-47b8-b1c6-fb0875ae1fdf'	System	11 Oct 2020 23:47:10
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(13)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b59ddc09-caa4-47b8-b1c6-fb0875ae1fdf'	System	11 Oct 2020 23:47:10
User entered '11 Oct 2020 18:47'	System	11 Oct 2020 23:47:10

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(13)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 11:24:11

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(13)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 11:24:11



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(14)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	11 Oct 2020 06:45:15
User entered 'Day 14'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(14)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '11bc627c-f9b4-4ff4-bfbe-3a997a07e3c3'	System	12 Oct 2020 20:39:47
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(14)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '11bc627c-f9b4-4ff4-bfbe-3a997a07e3c3'	System	12 Oct 2020 20:39:47
User entered '12 Oct 2020 15:39'	System	12 Oct 2020 20:39:47

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(14)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 06:45:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(14)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 06:45:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(15)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	11 Oct 2020 23:47:10
User entered 'Day 15'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(15)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(15)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(15)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 23:47:10

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(15)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(16)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	12 Oct 2020 20:39:47
User entered 'Day 16'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(16)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51768654-d6da-49b3-9a35-4488fa76e89e'	System	14 Oct 2020 21:50:32
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(16)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51768654-d6da-49b3-9a35-4488fa76e89e'	System	14 Oct 2020 21:50:32
User entered '14 Oct 2020 16:50'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(16)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:39:47

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(16)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(17)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 17'	System	14 Oct 2020 21:50:32



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(17)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9faa4696-6613-4a76-98f9-72d6567a56e3'	System	15 Oct 2020 19:21:16
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	15 Oct 2020 19:21:16

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(17)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9faa4696-6613-4a76-98f9-72d6567a56e3'	System	15 Oct 2020 19:21:16
User entered '15 Oct 2020 14:21'	System	15 Oct 2020 19:21:16

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(17)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(17)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(18)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 18'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(18)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(18)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(18)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:50:32



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(18)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(19)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	15 Oct 2020 19:21:16
User entered 'Day 19'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(19)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fbfe020e-9150-4ae6-9232-c0fe0f8fbb16'	System	18 Oct 2020 16:33:55
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(19)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fbfe020e-9150-4ae6-9232-c0fe0f8fbb16'	System	18 Oct 2020 16:33:55
User entered '18 Oct 2020 11:33'	System	18 Oct 2020 16:33:55

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(19)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:21:16

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(19)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:21:16

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 20'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(20)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '19 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(21)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 21'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(21)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a4b18397-fd42-4872-acab-0bd61b96ceaf'	System	19 Oct 2020 21:20:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(21)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a4b18397-fd42-4872-acab-0bd61b96ceaf'	System	19 Oct 2020 21:20:15
User entered '19 Oct 2020 16:20'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(21)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(21)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 16:33:55



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(22)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 22'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(22)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(22)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(22)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(22)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(23)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 23'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(23)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a8118ea9-aac0-44c2-93aa-6aa23c598560'	System	21 Oct 2020 19:09:39
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(23)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a8118ea9-aac0-44c2-93aa-6aa23c598560'	System	21 Oct 2020 19:09:39
User entered '21 Oct 2020 14:09'	System	21 Oct 2020 19:09:39



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(23)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(23)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(24)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 24'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(24)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '73f568fc-b655-49de-afd5-ae4d69b61f93'	System	22 Oct 2020 18:12:37
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(24)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '73f568fc-b655-49de-afd5-ae4d69b61f93'	System	22 Oct 2020 18:12:37
User entered '22 Oct 2020 13:12'	System	22 Oct 2020 18:12:37

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(24)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(24)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(25)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 25'	System	21 Oct 2020 19:09:39



US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(25)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c162f6a3-8f54-48d2-be73-893a8c00a37e'	System	24 Oct 2020 08:43:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(25)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c162f6a3-8f54-48d2-be73-893a8c00a37e'	System	24 Oct 2020 08:43:50
User entered '24 Oct 2020 03:43'	System	24 Oct 2020 08:43:50

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(25)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(25)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(26)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	22 Oct 2020 18:12:37
User entered 'Day 26'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(26)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cc612f58-dccf-4370-a839-f9b720cc098c'	System	24 Oct 2020 17:00:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(26)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cc612f58-dccf-4370-a839-f9b720cc098c'	System	24 Oct 2020 17:00:52
User entered '24 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(26)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:12:37



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(26)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:12:37

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(27)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	24 Oct 2020 08:43:50
User entered 'Day 27'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(27)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1c608be3-a8fe-4b18-a9a0-c56ebcbabb1f'	System	26 Oct 2020 03:01:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(27)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1c608be3-a8fe-4b18-a9a0-c56ebcbabb1f'	System	26 Oct 2020 03:01:41
User entered '25 Oct 2020 22:01'	System	26 Oct 2020 03:01:41

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(27)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 08:43:50

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(27)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 08:43:50

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(28)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	24 Oct 2020 17:00:52
User entered 'Day 28'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(28)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5bc02eaf-8238-47ee-bef4-5a12a05dde04'	System	26 Oct 2020 18:00:46
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	26 Oct 2020 18:00:46



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(28)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5bc02eaf-8238-47ee-bef4-5a12a05dde04'	System	26 Oct 2020 18:00:46
User entered '26 Oct 2020 13:00'	System	26 Oct 2020 18:00:46

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(28)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(28)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:00:52

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(29)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	26 Oct 2020 03:01:41
User entered 'Day 29'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(29)

Generated On: 10 Jun 2021 08:16:20

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9bbbcfd5-1313-4fd7-9d8a-8b67f50724e7'	System	27 Oct 2020 23:35:43
User entered 'None (0)'	System	27 Oct 2020 23:35:43

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(29)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9bbbcfd5-1313-4fd7-9d8a-8b67f50724e7'	System	27 Oct 2020 23:35:43
User entered '27 Oct 2020 18:35'	System	27 Oct 2020 23:35:43

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(29)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 03:01:41

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(29)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 03:01:41



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:45:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b271f1d1-401f-4216-8ce2-6b34999a6672'	System	06 Oct 2020 17:46:13
User entered 'No (N)'	System	06 Oct 2020 17:46:13

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b271fld1-401f-4216-8ce2-6b34999a6672'	System	06 Oct 2020 17:46:13
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:13

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 10'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:17:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '342f2bb3-13f9-44c2-a5b7-ee2f03b314cf'	System	08 Oct 2020 21:18:00
User entered 'No (N)'	System	08 Oct 2020 21:18:00

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:17:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '342f2bb3-13f9-44c2-a5b7-ee2f03b314cf' User entered '08 Oct 2020 16:17'	System	08 Oct 2020 21:18:00
	System	08 Oct 2020 21:18:00



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	07 Oct 2020 20:28:09
User entered 'Day 11'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:23:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'dc713972-1af2-419c-a9f5-40e86a13ba43'	System	10 Oct 2020 11:23:59
User entered 'No (N)'	System	10 Oct 2020 11:23:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:23:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'dc713972-1af2-419c-a9f5-40e86a13ba43'	System	10 Oct 2020 11:23:59
User entered '10 Oct 2020 06:23'	System	10 Oct 2020 11:23:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:28:09

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	08 Oct 2020 21:18:12
User entered 'Day 12'	System	08 Oct 2020 21:18:12



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:44:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c9b743d0-80ea-48e2-96bb-d55a26b788f9'	System	11 Oct 2020 06:44:58
User entered 'No (N)'	System	11 Oct 2020 06:44:58

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:44:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c9b743d0-80ea-48e2-96bb-d55a26b788f9'	System	11 Oct 2020 06:44:58
User entered '11 Oct 2020 01:44'	System	11 Oct 2020 06:44:58

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:18:12

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	10 Oct 2020 11:24:11
User entered 'Day 13'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '63938cba-d77d-4634-a2bd-3093591ae786'	System	11 Oct 2020 23:47:23
User entered 'No (N)'	System	11 Oct 2020 23:47:23

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:20', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '63938cba-d77d-4634-a2bd-3093591ae786'	System	11 Oct 2020 23:47:23
User entered '11 Oct 2020 18:47'	System	11 Oct 2020 23:47:23

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 11:24:11



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	11 Oct 2020 06:45:15
User entered 'Day 14'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '000869d6-26f1-4394-888d-69d050f6e943'	System	12 Oct 2020 20:39:54
User entered 'No (N)'	System	12 Oct 2020 20:39:54

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '000869d6-26f1-4394-888d-69d050f6e943'	System	12 Oct 2020 20:39:54
User entered '12 Oct 2020 15:39'	System	12 Oct 2020 20:39:54

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 06:45:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 06:45:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	11 Oct 2020 23:47:10
User entered 'Day 15'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14



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Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

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Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 23:47:10

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	12 Oct 2020 20:39:47
User entered 'Day 16'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e0d2b8f1-9fd3-40b1-b725-f9e3765e7e88'	System	14 Oct 2020 21:50:43
User entered 'No (N)'	System	14 Oct 2020 21:50:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e0d2b8f1-9fd3-40b1-b725-f9e3765e7e88'	System	14 Oct 2020 21:50:43
User entered '14 Oct 2020 16:50'	System	14 Oct 2020 21:50:43

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:39:47

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:39:47



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 17'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b1dbc19e-4d3d-4583-aecb-58d79c79b7c1'	System	15 Oct 2020 19:21:27
User entered 'No (N)'	System	15 Oct 2020 19:21:27

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b1dbc19e-4d3d-4583-aecb-58d79c79b7c1'	System	15 Oct 2020 19:21:27
User entered '15 Oct 2020 14:21'	System	15 Oct 2020 19:21:27

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 18'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	15 Oct 2020 19:21:16
User entered 'Day 19'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'df2b48c9-0aa6-44f1-80a9-fe3b3a6c1c7f'	System	18 Oct 2020 16:34:04
User entered 'No (N)'	System	18 Oct 2020 16:34:04

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:34:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'df2b48c9-0aa6-44f1-80a9-fe3b3a6c1c7f'	System	18 Oct 2020 16:34:04
User entered '18 Oct 2020 11:34'	System	18 Oct 2020 16:34:04

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:21:16

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 20'	System	18 Oct 2020 16:33:55



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

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Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '19 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 21'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '48390f98-62af-44ff-9f40-2473ec296835'	System	19 Oct 2020 21:20:24
User entered 'Yes (Y)'	System	19 Oct 2020 21:20:24

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '48390f98-62af-44ff-9f40-2473ec296835'	System	19 Oct 2020 21:20:24
User entered '19 Oct 2020 16:20'	System	19 Oct 2020 21:20:24

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 16:33:55



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 22'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 23'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35f1ad56-1983-473f-93c2-9b4a66accb36'	System	21 Oct 2020 19:09:50
User entered 'No (N)'	System	21 Oct 2020 19:09:50



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35f1ad56-1983-473f-93c2-9b4a66accb36'	System	21 Oct 2020 19:09:50
User entered '21 Oct 2020 14:09'	System	21 Oct 2020 19:09:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 24'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '40dc99c9-b1ef-48d1-bd46-93a78da7426a'	System	22 Oct 2020 18:12:43
User entered 'Yes (Y)'	System	22 Oct 2020 18:12:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '40dc99c9-b1ef-48d1-bd46-93a78da7426a'	System	22 Oct 2020 18:12:43
User entered '22 Oct 2020 13:12'	System	22 Oct 2020 18:12:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:09:39



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 25'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '996e7b6d-5885-4fce-84ce-8c5c0fac9446'	System	24 Oct 2020 08:43:56
User entered 'Yes (Y)'	System	24 Oct 2020 08:43:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '996e7b6d-5885-4fce-84ce-8c5c0fac9446'	System	24 Oct 2020 08:43:56
User entered '24 Oct 2020 03:43'	System	24 Oct 2020 08:43:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	22 Oct 2020 18:12:37
User entered 'Day 26'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '64663a4d-51ee-42c4-954e-df0e50e363b7'	System	24 Oct 2020 17:00:56
User entered 'No (N)'	System	24 Oct 2020 17:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '64663a4d-51ee-42c4-954e-df0e50e363b7'	System	24 Oct 2020 17:00:56
User entered '24 Oct 2020 12:00'	System	24 Oct 2020 17:00:56



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	24 Oct 2020 08:43:50
User entered 'Day 27'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4f0cebe7-c65e-4a7a-b22c-343f1db712cc'	System	26 Oct 2020 03:01:49
User entered 'No (N)'	System	26 Oct 2020 03:01:49

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4f0cebe7-c65e-4a7a-b22c-343f1db712cc'	System	26 Oct 2020 03:01:49
User entered '25 Oct 2020 22:01'	System	26 Oct 2020 03:01:49

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 08:43:50

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	24 Oct 2020 17:00:52
User entered 'Day 28'	System	24 Oct 2020 17:00:52



US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '81bcfa6c-ce96-4403-aade-7628825a8b18'	System	26 Oct 2020 18:00:56
User entered 'No (N)'	System	26 Oct 2020 18:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '81bcfa6c-ce96-4403-aade-7628825a8b18'	System	26 Oct 2020 18:00:56
User entered '26 Oct 2020 13:00'	System	26 Oct 2020 18:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 10 Jun 2021 08:16:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:00:52

**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
Data entry locked.	System	26 Oct 2020 03:01:41
User entered 'Day 29'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 10 Jun 2021 08:16:20

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)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0008b906-68f6-4a01-a876-c912d715633f'	System	27 Oct 2020 23:35:51
User entered 'No (N)'	System	27 Oct 2020 23:35:51

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 10 Jun 2021 08:16:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0008b906-68f6-4a01-a876-c912d715633f'	System	27 Oct 2020 23:35:51
User entered '27 Oct 2020 18:35'	System	27 Oct 2020 23:35:51

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 10 Jun 2021 08:16:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 03:01:41



**US3572134**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 10 Jun 2021 08:16:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:14
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 03:01:41

**US3572134**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 22:32:21

**US3572134**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '6 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 22:32:21

**US3572134**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 22:32:21

**US3572134**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 22:32:21

US3572134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 22:32:27

**US3572134**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'l'	System	06 Oct 2020 22:32:27

**US3572134**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	13 Oct 2020 21:55:42



**US3572134**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '13 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	13 Oct 2020 21:55:42

**US3572134**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	13 Oct 2020 21:55:42

**US3572134**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jessica McDowell (b) (4)	13 Oct 2020 21:55:42

US3572134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	13 Oct 2020 21:55:54

**US3572134**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'l'	System	13 Oct 2020 21:55:54

**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Oct 2020 16:50:02

**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '20 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	20 Oct 2020 16:50:02

**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	20 Oct 2020 16:50:02



**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered empty.	(b) (4) Jessica McDowell (b) (4)	20 Oct 2020 16:50:02

**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Oct 2020 16:51:01

**US3572134**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'l'	System	20 Oct 2020 16:51:01

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Oct 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'VISIT3'	System	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50



**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Oct 2020'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '10:21'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Oct 2020 10:21'	System	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User closed query 'Per CDM: Reported value is considered as Moderate( Grade 2) per CCGs. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Mar 2021 09:53:39
Query 'Per CDM: Reported value is considered as Moderate( Grade 2) per CCGs. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, Updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 22:21:19
User opened query 'Per CDM: Reported value is considered as Moderate( Grade 2) per CCGs. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 11:38:43
User entered '129'	(b) (4), (b) (6)	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'bpm'	System	26 Feb 2021 21:54:50



US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '18'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'breaths/min'	System	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '142'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '92'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:54:50

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'mmHg'	System	26 Feb 2021 21:54:50

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25



US3572134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:07:35

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:16:20**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Oct 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:07:35

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '28 Oct 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered '10:30'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered '28 Oct 2020 10:30'	System	06 Nov 2020 01:08:12

US3572134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:13:01
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:18

**US3572134**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'I'	System	06 Nov 2020 01:08:18



US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 64'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[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)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'Yes (Y)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

Have you been exposed to someone with 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)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'No (N)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'No (N)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'Yes (Y)'	System	28 Oct 2020 15:14:23

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:14:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 15:14:23

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:14:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered '28 Oct 2020 10:14:12'	System	28 Oct 2020 15:14:23

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 18:36:26



**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 71'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[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)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:40:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'Yes (Y)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

Have you been exposed to someone with 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)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:40:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered '06 Nov 2020 11:41:19'	System	06 Nov 2020 17:41:23

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 18:36:26



**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:20:19
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 78'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54



US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:57:54
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 18:36:26

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'Yes (Y)'	System	22 Nov 2020 21:14:20

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'No (N)'	System	22 Nov 2020 21:14:20



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'No (N)'	System	22 Nov 2020 21:14:20

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'Yes (Y)'	System	22 Nov 2020 21:14:20

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (09ef9a7cf96a439e)', Time: '2020-11-22T15:14:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 21:14:20

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:14:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered '22 Nov 2020 15:14:10'	System	22 Nov 2020 21:14:20

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2020-12-28T16:05:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ec96dfe9-3ab8-49f7-94d6-47e57d212745'	System	28 Dec 2020 22:05:53
User entered 'No (N)'	System	28 Dec 2020 22:05:53

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2020-12-28T16:05:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ec96dfe9-3ab8-49f7-94d6-47e57d212745'	System	28 Dec 2020 22:05:53
User entered 'No (N)'	System	28 Dec 2020 22:05:53

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2020-12-28T16:05:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ec96dfe9-3ab8-49f7-94d6-47e57d212745' User entered '28 Dec 2020 16:05:49'	System	28 Dec 2020 22:05:53
	System	28 Dec 2020 22:05:53

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-03T16:52:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ldbef7b-178a-4d78-a5e7-82ac2937f79a'	System	03 Jan 2021 22:52:42
User entered 'No (N)'	System	03 Jan 2021 22:52:42

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-01-03T16:52:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ldbef7b-178a-4d78-a5e7-82ac2937f79a'	System	03 Jan 2021 22:52:42
User entered 'No (N)'	System	03 Jan 2021 22:52:42

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-01-03T16:52:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ldbef7b-178a-4d78-a5e7-82ac2937f79a' User entered '03 Jan 2021 16:52:41'	System	03 Jan 2021 22:52:42

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-12T12:23:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '93eb4142-8820-4594-9220-7e1ff87f4a89'	System	12 Jan 2021 18:23:18
User entered 'No (N)'	System	12 Jan 2021 18:23:18



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-01-12T12:23:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '93eb4142-8820-4594-9220-7e1ff87f4a89'	System	12 Jan 2021 18:23:18
User entered 'No (N)'	System	12 Jan 2021 18:23:18

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-01-12T12:23:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '93eb4142-8820-4594-9220-7e1ff87f4a89' User entered '12 Jan 2021 12:23:15'	System	12 Jan 2021 18:23:18
	System	12 Jan 2021 18:23:18

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-18T07:53:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '659b662b-886c-463f-94ad-674c76e2ff43'	System	18 Jan 2021 13:53:40
User entered 'No (N)'	System	18 Jan 2021 13:53:40

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-01-18T07:53:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '659b662b-886c-463f-94ad-674c76e2ff43'	System	18 Jan 2021 13:53:40
User entered 'No (N)'	System	18 Jan 2021 13:53:40

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-01-18T07:53:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '659b662b-886c-463f-94ad-674c76e2ff43' User entered '18 Jan 2021 07:53:37'	System	18 Jan 2021 13:53:40



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-26T07:13:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb991ef3-8fbf-4343-a53e-5d7341396584'	System	26 Jan 2021 13:13:37
User entered 'No (N)'	System	26 Jan 2021 13:13:37

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-01-26T07:13:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb991ef3-8fbf-4343-a53e-5d7341396584'	System	26 Jan 2021 13:13:37
User entered 'No (N)'	System	26 Jan 2021 13:13:37

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-01-26T07:13:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb991ef3-8fbf-4343-a53e-5d7341396584' User entered '26 Jan 2021 07:13:33'	System	26 Jan 2021 13:13:37
	System	26 Jan 2021 13:13:37

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-31T07:09:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0cb0a1b0-e926-4d32-9fb0-37de7aca2911'	System	31 Jan 2021 13:09:56
User entered 'Yes (Y)'	System	31 Jan 2021 13:09:56

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-01-31T07:09:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0cb0a1b0-e926-4d32-9fb0-37de7aca2911'	System	31 Jan 2021 13:09:56
User entered 'No (N)'	System	31 Jan 2021 13:09:56

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-31T07:09:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0cb0a1b0-e926-4d32-9fb0-37de7aca2911'	System	31 Jan 2021 13:09:56
User entered 'No (N)'	System	31 Jan 2021 13:09:56

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-01-31T07:09:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0cb0a1b0-e926-4d32-9fb0-37de7aca2911'	System	31 Jan 2021 13:09:56
User entered 'No (N)'	System	31 Jan 2021 13:09:56

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-01-31T07:09:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0cb0a1b0-e926-4d32-9fb0-37de7aca2911' User entered '31 Jan 2021 07:09:53'	System	31 Jan 2021 13:09:56
	System	31 Jan 2021 13:09:56

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (f40df6ced40a04d3)', Time: '2021-02-14T11:05:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a3fc467c-e212-4c81-b102-6085497b53df'	System	14 Feb 2021 17:11:39
User entered 'No (N)'	System	14 Feb 2021 17:11:39

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (f40df6ced40a04d3)', Time: '2021-02-14T11:06:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a3fc467c-e212-4c81-b102-6085497b53df'	System	14 Feb 2021 17:11:39
User entered 'No (N)'	System	14 Feb 2021 17:11:39

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f40df6ced40a04d3)', Time: '2021-02-14T11:06:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a3fc467c-e212-4c81-b102-6085497b53df' User entered '14 Feb 2021 11:06:21'	System	14 Feb 2021 17:11:39

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-11T13:55:54-06:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '762f858e-0e9b-4ec5-812d-ce6029cbeaf2'	System	11 Mar 2021 19:56:19
User entered 'No (N)'	System	11 Mar 2021 19:56:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-03-11T13:56:02-06:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '762f858e-0e9b-4ec5-812d-ce6029cbeaf2'	System	11 Mar 2021 19:56:19
User entered 'No (N)'	System	11 Mar 2021 19:56:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-11T13:56:07-06:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '762f858e-0e9b-4ec5-812d-ce6029cbeaf2'	System	11 Mar 2021 19:56:19
User entered '11 Mar 2021 13:56:07'	System	11 Mar 2021 19:56:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-15T06:17:30-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8b430881-8c8c-46c9-a264-c801f602b2f9'	System	15 Mar 2021 11:17:42
User entered 'No (N)'	System	15 Mar 2021 11:17:42

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-03-15T06:17:35-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8b430881-8c8c-46c9-a264-c801f602b2f9'	System	15 Mar 2021 11:17:42
User entered 'No (N)'	System	15 Mar 2021 11:17:42



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-15T06:17:39-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8b430881-8c8c-46c9-a264-c801f602b2f9' User entered '15 Mar 2021 06:17:39'	System	15 Mar 2021 11:17:42
	System	15 Mar 2021 11:17:42

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:23:01-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'Yes (Y)'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:23:12-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a'	System	21 Mar 2021 13:25:33
User entered 'No (N)'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:23:26-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'Yes (Y)'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '0'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'l'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:24:55-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a'	System	21 Mar 2021 13:25:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:25:06-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered 'Yes (Y)'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (d3d66c8f294b3a39)', Time: '2021-03-21T08:25:17-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a'	System	21 Mar 2021 13:25:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-21T08:25:22-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '62d434ae-9eef-498c-85f1-452431e5f78a' User entered '21 Mar 2021 08:25:22'	System	21 Mar 2021 13:25:33
	System	21 Mar 2021 13:25:33

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-28T02:11:30-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011'	System	28 Mar 2021 07:12:19
User entered 'Yes (Y)'	System	28 Mar 2021 07:12:19



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-03-28T02:11:36-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011'	System	28 Mar 2021 07:12:19
User entered 'No (N)'	System	28 Mar 2021 07:12:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-28T02:11:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011'	System	28 Mar 2021 07:12:19
User entered 'No (N)'	System	28 Mar 2021 07:12:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-03-28T02:11:57-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011' User entered 'Yes (Y)'	System	28 Mar 2021 07:12:19
	System	28 Mar 2021 07:12:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (d3d66c8f294b3a39)', Time: '2021-03-28T02:12:04-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011'	System	28 Mar 2021 07:12:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 07:12:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-28T02:12:08-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c49fa63-3eb7-4153-94ca-6a383bad7011' User entered '28 Mar 2021 02:12:08'	System	28 Mar 2021 07:12:19
	System	28 Mar 2021 07:12:19

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-04T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b80c5ee3-f147-4277-aadc-3f0cd1d03db3'	System	04 Apr 2021 05:01:45
User entered 'No (N)'	System	04 Apr 2021 05:01:45

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-04-04T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b80c5ee3-f147-4277-aadc-3f0cd1d03db3'	System	04 Apr 2021 05:01:45
User entered 'No (N)'	System	04 Apr 2021 05:01:45

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-04-04T00:01:43-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b80c5ee3-f147-4277-aadc-3f0cd1d03db3' User entered '04 Apr 2021 00:01:43'	System	04 Apr 2021 05:01:45
	System	04 Apr 2021 05:01:45

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-12T03:17:32-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered 'Yes (Y)'	System	12 Apr 2021 08:18:15

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-04-12T03:17:37-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered 'No (N)'	System	12 Apr 2021 08:18:15



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-12T03:17:44-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered 'No (N)'	System	12 Apr 2021 08:18:15

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-12T03:17:54-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered 'Yes (Y)'	System	12 Apr 2021 08:18:15

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (d3d66c8f294b3a39)', Time: '2021-04-12T03:17:59-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Apr 2021 08:18:15

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-04-12T03:18:03-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35360ec7-1cf0-46ed-bc3c-7d0136e97f7a'	System	12 Apr 2021 08:18:15
User entered '12 Apr 2021 03:18:03'	System	12 Apr 2021 08:18:15

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:09-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered 'Yes (Y)'	System	18 Apr 2021 17:51:58



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:20-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered 'No (N)'	System	18 Apr 2021 17:51:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:29-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered 'No (N)'	System	18 Apr 2021 17:51:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:40-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered 'Yes (Y)'	System	18 Apr 2021 17:51:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Please 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 (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:46-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 17:51:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-04-18T12:51:50-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '71ed06b2-703e-41a8-8ead-d46f0dddc596'	System	18 Apr 2021 17:51:58
User entered '18 Apr 2021 12:51:50'	System	18 Apr 2021 17:51:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-04-25T21:54:08-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5c51e8f5-9e48-4f22-8a3b-0c0c9911af86'	System	26 Apr 2021 02:55:58
User entered 'No (N)'	System	26 Apr 2021 02:55:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-04-25T21:54:13-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5c51e8f5-9e48-4f22-8a3b-0c0c9911af86'	System	26 Apr 2021 02:55:58
User entered 'No (N)'	System	26 Apr 2021 02:55:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-04-25T21:54:16-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5c51e8f5-9e48-4f22-8a3b-0c0c9911af86'	System	26 Apr 2021 02:55:58
User entered '25 Apr 2021 21:54:16'	System	26 Apr 2021 02:55:58

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[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 (d3d66c8f294b3a39)', Time: '2021-05-02T13:21:36-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '97e40426-30e5-4e07-8981-29eb7a7a6dae' User entered 'No (N)'	System	02 May 2021 18:21:47

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

Have you been exposed to someone with 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 (d3d66c8f294b3a39)', Time: '2021-05-02T13:21:41-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '97e40426-30e5-4e07-8981-29eb7a7a6dae'	System	02 May 2021 18:21:47
User entered 'No (N)'	System	02 May 2021 18:21:47



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-05-02T13:21:44-05:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '97e40426-30e5-4e07-8981-29eb7a7a6dae'	System	02 May 2021 18:21:47
User entered '02 May 2021 13:21:44'	System	02 May 2021 18:21:47

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:57:54



**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

**US3572134**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:16:20**

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 16:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-11T13:55:12-06:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c6386325-9897-45d0-8f05-1b5cf47a1555'	System	11 Mar 2021 19:55:36
User entered 'No (N)'	System	11 Mar 2021 19:55:36

**US3572134**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d3d66c8f294b3a39)', Time: '2021-03-11T13:55:16-06:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c6386325-9897-45d0-8f05-1b5cf47a1555'	System	11 Mar 2021 19:55:36
User entered '11 Mar 2021 13:55:16'	System	11 Mar 2021 19:55:36

**US3572134**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:15:24
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	23 Nov 2020 15:25:11



**US3572134**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:15:24
User entered '23 Nov 2020'	(b) (4) Jessica McDowell (b) (4)	23 Nov 2020 15:25:11

**US3572134**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:15:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	23 Nov 2020 15:25:11

**US3572134**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:15:24
User entered empty.	(b) (4) Jessica McDowell (b) (4)	23 Nov 2020 15:25:11

US3572134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:15:24
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	23 Nov 2020 15:25:01

**US3572134**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:58:25
User entered 'l'	System	23 Nov 2020 15:25:01

**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	28 Dec 2020 14:56:33

**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '28 Dec 2020'	(b) (4) Jessica McDowell (b) (4)	28 Dec 2020 14:56:33

**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	28 Dec 2020 14:56:33



**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	28 Dec 2020 14:56:33

**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	28 Dec 2020 14:56:23

**US3572134**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User entered 'l'	System	28 Dec 2020 14:56:23

US3572134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 09-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:06:51
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 09-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	22 Feb 2021 22:16:56
' answered with 'swab collected 09FEB21 entered into EDC for PDV' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 09-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	19 Feb 2021 06:26:07
' (Site from DM). User entered 'Yes (Y)'	Jessica McDowell (b) (4)	25 Jan 2021 19:43:47

**US3572134**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '25 Jan 2021'	(b) (4) Jessica McDowell (b) (4)	25 Jan 2021 19:43:47

**US3572134**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	25 Jan 2021 19:43:47

US3572134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	25 Jan 2021 19:43:47

**US3572134**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	25 Jan 2021 19:43:51



**US3572134**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User entered 'l'	System	25 Jan 2021 19:43:51

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 14:57:01

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '23 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 14:57:01

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 14:57:01

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Feb 2021 14:57:01

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 14:57:05

**US3572134**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:55:04
User entered 'l'	System	23 Feb 2021 14:57:05

US3572134

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 23:36:50



**US3572134**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 23:36:50

US3572134

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 23:36:58

US3572134

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '26 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 23:36:58

US3572134

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 23:36:58

**US3572134**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 23:36:58

US3572134

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	26 Apr 2021 23:37:02

**US3572134**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 23:37:02

US3572134

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:17:20



**US3572134**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '09 Feb 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:17:20

US3572134

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[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 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:20

**US3572134**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 22:17:20

US3572134

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:16:20**

[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 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:14:19

US3572134

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) System	22 Feb 2021 22:25:35
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	22 Feb 2021 22:25:35
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	22 Feb 2021 22:17:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:16:20**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
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 14:14:19

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:48



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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:25:35
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:17:48

US3572134

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:48

US3572134

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:48

US3572134

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:16:20**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'I'	System	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'I'	System	22 Feb 2021 22:17:48

US3572134

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29



US3572134

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered empty.	System	22 Feb 2021 22:19:29
DataPoint set to visible.	System	22 Feb 2021 22:17:48

US3572134

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

**US3572134**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:16:20**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered empty.	System	22 Feb 2021 22:19:29
DataPoint set to visible.	System	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '12 Feb 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:19:29

**US3572134**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '16:45'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:19:29



**US3572134**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered '12 Feb 2021 16:45'	System	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:05
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	22 Feb 2021 22:20:05
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:05
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

**US3572134**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'bpm'	System	22 Feb 2021 22:20:05
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:05
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'breaths/min'	System	22 Feb 2021 22:20:05
User entered empty.	System	22 Feb 2021 22:19:29



US3572134

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:05
User entered '141' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'mmHg'	System	22 Feb 2021 22:20:05
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:05
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:05
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'mmHg'	System	22 Feb 2021 22:20:05
User entered empty.	System	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered empty.	System	22 Feb 2021 22:19:29
DataPoint set to visible.	System	22 Feb 2021 22:17:48

**US3572134**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Feb 2021 22:19:29



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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '12 Feb 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '18:10'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:19:29

**US3572134**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered '12 Feb 2021 18:10'	System	22 Feb 2021 22:19:29

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:44
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	22 Feb 2021 22:20:44
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 22:20:44
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:44
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29



**US3572134**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'bpm'	System	22 Feb 2021 22:20:44
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:44
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'breaths/min'	System	22 Feb 2021 22:20:44
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:44
User entered '131' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'mmHg'	System	22 Feb 2021 22:20:44
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:20:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Feb 2021 22:20:44
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 22:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 22:19:29
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:19:29

US3572134

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'mmHg'	System	22 Feb 2021 22:20:44
User entered empty.	System	22 Feb 2021 22:19:29

US3572134

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:20:53



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

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:20:53

**US3572134**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:16:20**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered 'mRNA-1273'	System	22 Feb 2021 22:21:21
DataPoint set to visible.	System	22 Feb 2021 22:17:48

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User closed query 'Per CDMRQ: please review both date in edc and IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:29:14
Query 'Per CDMRQ: please review both date in edc and IRT and update accordingly' answered with 'per source date is 12feb2021' (Site from DM).	Caitlin roll (b) (4)	16 Apr 2021 15:11:45
User opened query 'Per CDMRQ: please review both date in edc and IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:50:58
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 13FEB2021. Please review and reconcile.	(b) (4), (b) (6)	15 Apr 2021 20:50:58
' (Site from DM).		
Query 'Per IRT, Subject had Open Label Day1 Treatment on 13FEB2021. Please review and reconcile.	(b) (4), (b) (6)	09 Apr 2021 16:14:56
' answered with 'Visit happened on 09FEB2021' (Site from DM).		
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 13FEB2021. Please review and reconcile.	(b) (4), (b) (6)	09 Apr 2021 11:11:47
' (Site from DM).		
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '12 Feb 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:21:21

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17:40'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered '12 Feb 2021 17:40'	System	22 Feb 2021 22:21:21



US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered 'ONCE'	System	22 Feb 2021 22:21:21

US3572134

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 22:21:21

US3572134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:18:13

US3572134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 09Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 09Feb2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'AWB - 939474286270 shipped 25Feb2021 Accession # - 1F60D4L' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 09Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:17:22
	(b) (4), (b) (6)	01 Mar 2021 22:29:59
	(b) (4), (b) (6)	25 Feb 2021 20:00:04
	(b) (4), (b) (6)	22 Feb 2021 22:18:13

US3572134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '15:11'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:18:13

**US3572134**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User entered '09 Feb 2021 15:11'	System	22 Feb 2021 22:18:13

US3572134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:18:36



US3572134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '09 Feb 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:18:36

**US3572134**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:16:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '15:09'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 22:18:36

**US3572134**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered '09 Feb 2021 15:09'	System	22 Feb 2021 22:18:36

US3572134

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

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:24:23

**US3572134**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:12:14
User entered 'I'	System	22 Feb 2021 22:24:23

**US3572134**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	09 Mar 2021 16:23:16

US3572134

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '19 Feb 2021'	(b) (4) Jessica McDowell (b) (4)	09 Mar 2021 16:23:16

US3572134

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	09 Mar 2021 16:23:16



US3572134

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	09 Mar 2021 16:23:16

US3572134

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 20:58:36
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	12 Mar 2021 17:50:44
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	09 Mar 2021 16:23:20
	(b) (4)	

**US3572134**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User entered 'l'	System	17 Mar 2021 20:58:36
User entered empty.	System	12 Mar 2021 17:50:44
User entered 'l'	System	09 Mar 2021 16:23:20

US3572134

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:17
User entered 'I'	System	17 Mar 2021 20:58:36
User entered empty.	System	12 Mar 2021 17:50:44
User entered 'I'	System	09 Mar 2021 16:23:20
DataPoint set to visible.	System	09 Mar 2021 16:23:20

US3572134

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:58:46

US3572134

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:58:46

**US3572134**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[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 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:58:46

**US3572134**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'OLD29'	System	17 Mar 2021 20:58:46



**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '14:15'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '17 Mar 2021 14:15'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29



**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '97'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'bpm'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'breaths/min'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '131'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '96'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	17 Mar 2021 21:00:29



**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '15:35'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '17 Mar 2021 15:35'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29



US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '89'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

**US3572134**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'bpm'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'breaths/min'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '126'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '89'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:29

US3572134

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	17 Mar 2021 21:00:29



US3572134

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:36

US3572134

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:00:36

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:09

**US3572134**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:16:20**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mRNA-1273'	System	17 Mar 2021 21:01:09
DataPoint set to visible.	System	17 Mar 2021 20:58:36

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:09

**US3572134**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '15:05'	(b) (4), (b) (6)	17 Mar 2021 21:01:09



**US3572134**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '17 Mar 2021 15:05'	System	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'ONCE'	System	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'INTRAMUSCULAR'	System	17 Mar 2021 21:01:09

US3572134

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 21:01:15

**US3572134**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'l'	System	17 Mar 2021 21:01:15

**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:32:54

**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '25 Mar 2021'	(b) (4) Jessica McDowell (b) (4) (b) (4)	25 Mar 2021 18:32:54



**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	25 Mar 2021 18:32:54

**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Jessica McDowell (b) (4) (b) (4)	25 Mar 2021 18:32:54

**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:33:04

**US3572134**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User entered 'l'	System	25 Mar 2021 18:33:04

US3572134

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:10:35

US3572134

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '19 Apr 2021'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:10:35

US3572134

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:10:35

**US3572134**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	28 Apr 2021 22:10:35



US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '19 Apr 2021'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '14:45'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 14:45'	System	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '98.2' F	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '82'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02



**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '18'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '130'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '96'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:02

**US3572134**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 22:12:02

US3572134

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:12



US3572134

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered empty.	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:12

US3572134

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:28

US3572134

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '19 Apr 2021'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:28

US3572134

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:33
User entered '14:52'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 22:12:28

**US3572134**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 14:52'	System	28 Apr 2021 22:12:28

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 08:16:20**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:01
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:11

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 08:16:20**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:01
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:11

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 08:16:20**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:01
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:11



**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 08:16:20**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:01
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:11

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 08:16:20**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:01
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:11

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:16:20**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:07
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:24

**US3572134**

**Folder: Unscheduled 22 Oct 2020**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:16:20**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:49:07
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:24

US3572134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:31
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:36
User closed query 'Per CDM: 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 DOSE 2 diary, Nausea/Vomiting (DAY 28) lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 22:57:47
User closed query 'Macrocytic anemia is not listed as an AE or Med Hx, please update as appropriate *(AM)' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 22:57:34
Query 'Macrocytic anemia is not listed as an AE or Med Hx, please update as appropriate *(AM)' answered with 'Macrocytic Anemia has been added to AE log' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 21:38:50
User closed query 'Per CDM: 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 DOSE 2 diary, Medical Attention (DAY 25) lasting beyond day 7 post injection. Please clarify if this AE represent the event reported. If so, please update start and end date to match and ensure SAR box is checked. If not, please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:06:27

US3572134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM: 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 DOSE 2 diary, Medical Attention (DAY 25) lasting beyond day 7 post injection. Please clarify if this AE represent the event reported. If so, please update start and end date to match and ensure SAR box is checked. If not, please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'updated unscheduled visit added to EDC ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 22:06:38
Query 'Per CDM: 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 DOSE 2 diary, Nausea/Vomiting (DAY 28) lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'ae log updated per diary dose' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 22:03:30
User closed query 'Per med records, multiple con meds were noted as prescribed at discharge. Please review and add all applicable con meds to EDC.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:45:25
User opened query 'Macrocytic anemia is not listed as an AE or Med Hx, please update as appropriate *(AM)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:44:45
User closed query 'Per med records, its noted subject has macrocytic anemia. Should this be added to AE log of med hx? Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:44:45
User closed query 'per med records, is fatty liver a new AE or to be added to med hx? Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:43:49
User closed query 'Per med records review of SAE "fall", please confirm if CT scans should be noted as procedures and findings from scans (fractures noted) are also added to EDC.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:24

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: 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 DOSE 2 diary, Nausea/Vomiting (DAY 28) lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 00:00:27
User opened query 'Per CDM: 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 DOSE 2 diary, Medical Attention (DAY 25) lasting beyond day 7 post injection. Please clarify if this AE represent the event reported. If so, please update start and end date to match and ensure SAR box is checked. If not, please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 23:48:31
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:42:55

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**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 08:16:20**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'updated' (Site from DM).	Jessica McDowell (b) (4)	07 Apr 2021 19:35:53
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:34:23
User closed query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:12:55
Query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:35:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 05:35:20
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:12:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:57:16



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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per med records, multiple con meds were noted as prescribed at discharge. Please review and add all applicable con meds to EDC.' answered with 'Data updated' (Site from CRA).	Maria Candelario (b) (4)	14 Feb 2021 20:20:02
Query 'Per med records, its noted subject has macrocytic anemia. Should this be added to AE log of med hx? Please review and reconcile.' answered with 'Data updaed' (Site from CRA).	Maria Candelario (b) (4)	14 Feb 2021 20:19:38
Query 'per med records, is fatty liver a new AE or to be added to med hx? Please review and reconcile.' answered with 'Med HX' (Site from CRA).	Maria Candelario (b) (4)	13 Feb 2021 23:31:02
Query '□ Per med records review of SAE "fall", please confirm if CT scans should be noted as procedures and findings from scans (fractures noted) are also added to EDC.' answered with 'Yes' (Site from CRA).	Maria Candelario (b) (4)	13 Feb 2021 23:30:34
User opened query 'Per med records, multiple con meds were noted as prescribed at discharge. Please review and add all applicable con meds to EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:20:23
User opened query 'Per med records, its noted subject has macrocytic anemia. Should this be added to AE log of med hx? Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:17:00
User opened query 'per med records, is fatty liver a new AE or to be added to med hx? Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:13:36
Query 'Per med records review of SAE "fall", please confirm if CT scan should be noted as completed on 09Nov in EDC and right humerus fracture noted as well.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:04:10
User opened query '□ Per med records review of SAE "fall", please confirm if CT scans should be noted as procedures and findings from scans (fractures noted) are also added to EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:04:05
User opened query 'Per med records review of SAE "fall", please confirm if CT scan should be noted as completed on 09Nov in EDC and right humerus fracture noted as well.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 18:02:42
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	11 Sep 2020 18:03:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Please review this AE and the following AEs: #4 VOMITING, #5 DIARRHEA, & #6 HEADACHE as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	19 Mar 2021 09:48:13
Query 'Per DM CLR: Please review this AE and the following AEs: #4 VOMITING, #5 DIARRHEA, & #6 HEADACHE as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' answered with 'Per source, there is no unifying diagnosis. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:05:39
User opened query 'Per DM CLR: Please review this AE and the following AEs: #4 VOMITING, #5 DIARRHEA, & #6 HEADACHE as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:46:45
User coded data point as SOC: Gastrointestinal disorders, HLG: 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 21:10:44
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 21:10:44
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
Data point term sent to Coder	System	18 Sep 2020 21:51:13

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'nausea'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:11:06
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' answered with 'Data updated ' (Site from DM).	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:55:15
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:54:57
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:31
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	17 Nov 2020 15:54:57
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:54:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 21:50:29
User entered '05:00'	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User entered empty.	System	17 Nov 2020 15:54:57
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	17 Nov 2020 15:55:37
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:55:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	18 Sep 2020 21:50:29
User entered '14:00'	System	18 Sep 2020 21:50:29
	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User entered empty.	System	17 Nov 2020 15:55:37
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:50:29
User entered empty.	System	18 Sep 2020 21:50:29
	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:50:29
User entered empty.	System	18 Sep 2020 21:50:29
	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:16:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:50:29
User entered empty.	System	18 Sep 2020 21:50:29
	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User entered '0'	System	18 Sep 2020 21:50:29

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19
User entered '0'	System	18 Sep 2020 21:50:29

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:51:41
Data point term sent to Coder	System	18 Sep 2020 21:51:14
User entered 'vomiting'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:11:23
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:57:06
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:45
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered '05:00'	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User entered empty.	System	17 Nov 2020 15:56:54
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:51:04

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered '14:00'	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User entered empty.	System	17 Nov 2020 15:56:54
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered empty.	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered empty.	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered empty.	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:04
User entered empty.	System	18 Sep 2020 21:51:04
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User entered '0'	System	17 Nov 2020 15:56:54



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23
User entered '0'	System	18 Sep 2020 21:51:04

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:23

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:53:39
Data point term sent to Coder	System	18 Sep 2020 21:52:17
User entered 'diarrhea'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:11:34
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Data Updated' (Site from DM).	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 16:12:10
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:58:17
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:52
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	17 Nov 2020 15:58:17
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:58:17
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	18 Sep 2020 21:51:31
User entered '05:00'	System	18 Sep 2020 21:51:31
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User entered empty.	System	17 Nov 2020 15:58:17
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Generated On: 10 Jun 2021 08:16:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	17 Nov 2020 15:58:17
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:58:17
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	18 Sep 2020 21:51:31
User entered '14:00'	System	18 Sep 2020 21:51:31
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User entered empty.	System	17 Nov 2020 15:58:17
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 16:00:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 16:00:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 16:00:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:31
User entered empty.	System	18 Sep 2020 21:51:31
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

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Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:58:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:58:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:31
User entered empty.	System	18 Sep 2020 21:51:31
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:16:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 15:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:58:17
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:58:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:51:31
User entered empty.	System	18 Sep 2020 21:51:31
	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User entered '0'	System	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31
User entered '0'	System	18 Sep 2020 21:51:31

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:31

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 19:22:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 19:22:55
Data point term sent to Coder	System	19 Feb 2021 19:22:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
Data point term sent to Coder	System	06 Oct 2020 22:37:39
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:54:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:54:39
Data point term sent to Coder	System	18 Sep 2020 21:53:19
User entered 'headache'	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	11 Mar 2021 09:32:53
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification.	(b) (4), (b) (6)	10 Mar 2021 15:20:02
' answered with 'DATA UPDATED ACCORDINGLY ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 15:19:33
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:57:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '17 Sep 2020'	(b) (4)	
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	19 Feb 2021 19:22:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	
User entered '05:00'	System	18 Sep 2020 21:52:43
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User entered empty.	System	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '17 Sep 2020 05:00'	(b) (4)	
	System	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	19 Feb 2021 19:22:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	18 Sep 2020 21:52:43
User entered '14:00'	System	18 Sep 2020 21:52:43
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User entered empty.	System	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '17 Sep 2020 14:00'	(b) (4)	
	System	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered empty.	(b) (4)	
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
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	19 Feb 2021 19:22:14
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Sep 2020 21:52:43
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 19:22:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 19:22:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:52:43
User entered empty.	System	18 Sep 2020 21:52:43
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
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	19 Feb 2021 19:22:14
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Sep 2020 21:52:43
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered '1'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4)	
	Jasmine Ali (b) (4)	18 Sep 2020 21:52:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 22:37:26
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) System	18 Sep 2020 21:52:43



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26
User entered '0'	(b) (4) System	18 Sep 2020 21:52:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Feb 2021 19:21:38
DataPoint inactivated with code reason code Data not required.	Jessica McDowell (b) (4)	06 Oct 2020 22:37:26

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
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).	(b) (4) (u) (4), (b) (6)	21 Dec 2020 08:35:13
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 'Subject symptoms are intermittent' (Site from DM).	Maria Candelario (b) (4) (b) (4)	18 Dec 2020 08:39:10
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)	15 Dec 2020 08:19:54
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
Data point term sent to Coder	System	06 Oct 2020 23:22:28
User entered 'diarrhea'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	20 Nov 2020 05:23:16
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 16:13:04
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 16:12:55
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:38
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '2 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User entered empty.	System	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	24 Nov 2020 17:21:33
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	24 Nov 2020 17:23:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Nov 2020 17:23:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 17:21:33
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User entered empty.	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User entered empty.	System	06 Oct 2020 23:22:20

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20



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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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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)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 09:34:21
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:23:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:01:55
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Not Related (NOT RELATED)'	(b) (4)	24 Nov 2020 17:21:33
reason for change: Data Entry Error	(u) (4), (b) (6)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4)	06 Oct 2020 23:22:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	24 Nov 2020 17:21:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'l'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	24 Nov 2020 17:23:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica McDowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR RQ: Narrative = SUBJECT DISCLOSED HE HAS A HISTORY OF GASTRIC BYPASS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4) (u) (4), (b) (6)	01 Mar 2021 07:55:53
Query 'Per DM CLR RQ: Narrative = SUBJECT DISCLOSED HE HAS A HISTORY OF GASTRIC BYPASS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'gastric bypass recorded on MH eCRF' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:21:10
User opened query 'Per DM CLR RQ: Narrative = SUBJECT DISCLOSED HE HAS A HISTORY OF GASTRIC BYPASS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:09:36
User closed query 'Per DM CLR: SAE Narrative = SUBJECT STATES SYMPTOM "COMES AND GOES". However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:09:36
Query 'Per DM CLR: SAE Narrative = SUBJECT STATES SYMPTOM "COMES AND GOES". However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4) (b) (4)	13 Feb 2021 23:25:40

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'The subject reported the Diarrhea started after Dose 2 (under protocol amendment 5) The subject had visit Day 1 OL (amendment 6) yesterday, he disclosed he has a history of Gastric bypass, this was not previously reported. Site made CRA aware' reason for change: Data Entry Error	Maria Candelario (b) (4)	13 Feb 2021 23:25:25
User opened query 'Per DM CLR: SAE Narrative = SUBJECT STATES SYMPTOM "COMES AND GOES". However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:06:15
User entered 'subject states symptom "comes and goes."'	Jessica McDowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User entered '0'	System	06 Oct 2020 23:22:20

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46
User entered '0'	System	06 Oct 2020 23:22:20

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:46

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:29:07
User entered 'USA-US091-2020-mRNA-1273-P301000003'	System	10 Nov 2020 21:13:58
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 21:13:58



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR RQ: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition. Otherwise clarify.' (Site from DM). Query 'Per DM CLR RQ: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition. Otherwise clarify.' answered with 'Fall was secondary to a seizure at home per hospital Medical Records.' (Site from DM).	(b) (4) (u) (4), (b) (6)	17 Mar 2021 06:28:02
User opened query 'Per DM CLR RQ: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:11:45
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:58:10
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:58:10
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 17:24:09
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of FREQUENT FALLS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:57:56

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Both the event onset date and resolution date was 08 Nov 2020. The seriousness criteria for the event included hospitalization with hospitalization dates of 09 Nov 2020 to 13 Nov 2020. Please confirm if this event "Fall" meets seriousness criteria of hospitalization. Additionally, please confirm if broken bones or other injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:53:37
Query 'PV Query: Both the event onset date and resolution date was 08 Nov 2020. The seriousness criteria for the event included hospitalization with hospitalization dates of 09 Nov 2020 to 13 Nov 2020. Please confirm if this event "Fall" meets seriousness criteria of hospitalization. Additionally, please confirm if broken bones or other injuries sustained from fall should be added as SAEs.' answered with 'The subject suffered a Humeral fracture secondary to the fall that took place on 08Nov2020. he presented to the ER on 09Nov2020.' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:06:25
User opened query 'PV Query: Both the event onset date and resolution date was 08 Nov 2020. The seriousness criteria for the event included hospitalization with hospitalization dates of 09 Nov 2020 to 13 Nov 2020. Please confirm if this event "Fall" meets seriousness criteria of hospitalization. Additionally, please confirm if broken bones or other injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:45:09
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 18:51:38
Data point term sent to Coder	System	10 Nov 2020 18:35:54
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 18:35:27
User entered 'Fall' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:35:27

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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: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 10:52:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 10:52:30
Data point term sent to Coder	System	09 Nov 2020 23:00:12
User entered 'Initial SAE report, Pending medical records	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
Fall'	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:36
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:34
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:33
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
	(b) (4)	
DataPoint Un-verified.	Maria Candelario (b) (4)	18 Dec 2020 08:42:42
	(b) (4)	
User entered '8 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4)	18 Dec 2020 08:42:42
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:31
User entered '9 Nov 2020'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:29
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:28
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 15:38:04
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:38:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 15:37:43
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Please review the duration of FALL. It is unusual for this condition to have a duration. Effects may continue but not the event itself. Please update and reconcile as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review the duration of FALL. It is unusual for this condition to have a duration. Effects may continue but not the event itself. Please update and reconcile as appropriate. Otherwise, clarify.' answered with 'Data updated' (Site from DM).	(b) (4) (u) (4), (b) (6)	21 Dec 2020 07:49:16
DataPoint Un-verified.	Maria Candelario (b) (4) (b) (4)	19 Dec 2020 02:08:47
User entered '8 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	18 Dec 2020 08:42:42
User opened query 'Per DM CLR: Please review the duration of FALL. It is unusual for this condition to have a duration. Effects may continue but not the event itself. Please update and reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 05:45:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:26
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 15:37:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 15:37:43
User entered '13 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:37:43
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 15:37:07
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:24
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:21
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	10 Nov 2020 18:36:52
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	09 Nov 2020 23:00:10
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:16
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:15
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:10:13
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)	12 Nov 2020 05:30:20
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 'Subject was admitted to the hospital on 11/09/2020 (per subject) and is still in the hospital. Records are pending.' (Site from System).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:25
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		10 Nov 2020 18:36:52
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		10 Nov 2020 18:36:52
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	10 Nov 2020 18:36:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:36:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Nov 2020 23:00:10
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'PV Query: Please confirm if the hospitalization that occurred on 09 Nov 2020 for fall after a seizure meets SAE reporting criteria.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	04 Mar 2021 14:53:58
Query 'PV Query: Please confirm if the hospitalization that occurred on 09 Nov 2020 for fall after a seizure meets SAE reporting criteria.'	Maria Candelario (b) (4)	03 Mar 2021 04:23:59
answered with 'already reported' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please confirm if the hospitalization that occurred on 09 Nov 2020 for fall after a seizure meets SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:45:56
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:11
User entered '9 Nov 2020'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:34:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent via email 19Jan2021' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 18:00:18
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:51:44
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:11
User entered '13 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	18 Nov 2020 00:49:18
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:09:07
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:09:06
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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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)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:09:04
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:09:02
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10



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Folder: Adverse Events

Form: Adverse Events (9)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:09:00
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:08:59
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:29:13
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:47
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:43:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:08:57
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:29:14
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:45
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:43:43
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	25 Nov 2020 20:32:18
Query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:38:36
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 02:36:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 02:36:57
User opened query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:21:24
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'None (NONE)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:08:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Nov 2020 15:26:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 23:00:10
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	04 Mar 2021 14:54:11
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Con- meds reported as per medical history' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:25:46
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:46:11
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 04:49:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Con-Med added on line #2.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:35:49
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 05:45:51

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:49
User entered '1' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	22 Feb 2021 06:16:51
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'Medical records were reviewed. There was no Con Proc done for the fall in specific. The only action taken was Con Meds, which are already recorded in the Con Med Log. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 19:19:29
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 19:13:32
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:13:32
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:55:29
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 04:49:59



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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con-procedures added as per hospital discharge report.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:56:14
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 05:45:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:47
User entered '1' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Form: Adverse Events (9)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:08:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:37:07
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Form: Adverse Events (9)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 13:08:43
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'PV Query: As hospitalization occurred after event resolution, please confirm the reason for hospitalization. Was the hospitalization prolonged due to another SAE?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 12:46:19
User closed query 'Per DM CLR RQ: Response says updated, however no update made. Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:28:49
Query 'PV Query: As hospitalization occurred after event resolution, please confirm the reason for hospitalization. Was the hospitalization prolonged due to another SAE?' answered with 'Per hospital medical records, "Pt was admitted and monitored for alcohol withdrawal signs and neuro consulted for seizures. Ortho consulted for fracture but due to extensive soft tissue swelling, no surgical intervention was done so as to wait for medical stabilization and swelling to go down."' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:28:19
Query 'Per DM CLR RQ: Response says updated, however no update made. Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Added as subject's MH.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:20:17
User opened query 'PV Query: As hospitalization occurred after event resolution, please confirm the reason for hospitalization. Was the hospitalization prolonged due to another SAE?' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 12:51:39

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Response says updated, however no update made. Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:01:13
User closed query 'Per DM CLR: Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:01:13
User closed query 'PV Query: per reported information the event ended and resolved prior to the subject's hospitalization. Please consider updating end date to the date all symptoms/treatment resolved. Else please clarify seriousness criteria, if event resolved prior to hospitalization, was the hospitalization prolonged due to another SAE?' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:18:28
Query 'PV Query: per reported information the event ended and resolved prior to the subject's hospitalization. Please consider updating end date to the date all symptoms/treatment resolved. Else please clarify seriousness criteria, if event resolved prior to hospitalization, was the hospitalization prolonged due to another SAE?' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:29:42
Query 'Per DM CLR: Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 17:29:18

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: per reported information the event ended and resolved prior to the subject's hospitalization. Please consider updating end date to the date all symptoms/treatment resolved. Else please clarify seriousness criteria, if event resolved prior to hospitalization, was the hospitalization prolonged due to another SAE?' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 13:29:36
User opened query 'Per DM CLR: Narrative = HISTORY OF ALCOHOLISM AND FATTY LIVER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:58:47
User closed query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:49:41
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	(b) (4), (b) (6)	16 Feb 2021 06:55:58
' (Site from DM).		
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	Maria Candelario (b) (4)	14 Feb 2021 20:19:07
' answered with 'Data updated' (Site from DM).	(b) (4)	
Query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.'	Maria Candelario (b) (4)	14 Feb 2021 20:19:00
answered with 'Data updated as per query ' (Site from Safety).	(b) (4)	
User entered 'Medical records were received for subject's hospitalization. Records indicate subject has a history of alcoholism and fatty liver. Records have no indication that subjects event has any causal relationship to IP.' reason for change: Data Entry Error	Maria Candelario (b) (4)	13 Feb 2021 23:30:18
(b) (4)	(b) (4)	

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Form: Adverse Events (9)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:38:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:37:56
User closed query 'PV Query: Please confirm if frequent falls, hard of hearing, and obesity(discharge diagnosis) should be added as MH.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:29:28
User closed query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:29:25
User closed query 'Per DM CLR: SAE Narrative = SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM.. However, please confirm if the start date should be updated to 08NOV2020. (previous night before the call). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 04:07:18
Query 'PV Query: Please confirm if frequent falls, hard of hearing, and obesity(discharge diagnosis) should be added as MH.' answered with 'Will add as MH. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:57:33
Query 'Per DM CLR: SAE Narrative = SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM.. However, please confirm if the start date should be updated to 08NOV2020. (previous night before the call). Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:55:06

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Folder: Adverse Events

Form: Adverse Events (9)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'Will add DIZZINESS to subject's MH.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 17:52:14
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.	(b) (4), (b) (6)	05 Feb 2021 17:50:44
SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020 AND WAS SCHEDULED FOR EVAL AT THE RESEARCH SITE FOR POSSIBLE COVID SWAB. SUBJECT DID NOT STAY AT CLINIC TO BE EVALUATED, AND LEFT TO GO TO WORK. SUBJECT WAS CONTACTED AND RESCHEDULED TO BE AT CLINIC ON 11/09/2020. HE CALLED INSTEAD AND NOTIFIED RESEARCH SITE THAT HE WAS IN THE HOSPITAL DUE TO A FALL DURING THE NIGHT AND HAS A LONG HISTORY OF DIZZINESS. HOSPITAL RECORDS ARE PENDING.		
17 NOV 2020, SUBJECT CALLED (b) (6) TO INFORM DISCHARGE FROM HOSPITAL ON 13 NOV 2020. SUBJECT WILL BE SCHEDULED TO COME TO SITE 18 NOV 2020, TO OBTAIN RELEASE RECORD SIGNATURE.' reason for change: Data Entry Error		
User opened query 'PV Query: Please confirm if frequent falls, hard of hearing, and obesity(discharge diagnosis) should be added as MH.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 15:34:51



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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:07:27
User opened query 'Per DM CLR: SAE Narrative = SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM.. However, please confirm if the start date should be updated to 08NOV2020. (previous night before the call). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 07:24:34
User opened query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:52:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:52:11
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:50:34
User opened query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:46:56
User closed query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:38
User closed query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:35
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:32:31
Query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:49:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:19

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:11
Query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:02
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:39:43
User opened query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:09
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:23:23
User opened query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:21:46
	(b) (4), (b) (6)	18 Nov 2020 13:08:42
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.	Maria Candelario (b) (4) (b) (4)	18 Nov 2020 00:51:33

SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020 AND WAS SCHEDULED FOR EVAL AT THE RESEARCH SITE FOR POSSIBLE COVID SWAB. SUBJECT DID NOT STAY AT CLINIC TO BE EVALUATED, AND LEFT TO GO TO WORK. SUBJECT WAS CONTACTED AND RESCHEDULED TO BE AT CLINIC ON 11/09/2020. HE CALLED INSTEAD AND NOTIFIED RESEARCH SITE THAT HE WAS IN THE HOSPITAL DUE TO A FALL DURING THE NIGHT AND HAS A LONG HISTORY OF DIZZINESS. HOSPITAL RECORDS ARE PENDING.

17 NOV 2020, SUBJECT CALLED (b) (6) TO INFORM DISCHARGE FROM HOSPITAL ON 13 NOV 2020. SUJECT WILL BE SCHEDULED TO COME TO SITE 18 NOV 2020, TO OBTAIN RESEALE RECORD SIGNATURE.' reason for change: Data Entry Error

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.  Subject had complained of nausea on 11/05/2020 and was scheduled for eval at the research site for possible Covid swab. Subject did not stay at clinic to be evaluated, and left to go to work. Subject was contacted and rescheduled to be at clinic on 11/09/2020. He called instead and notified research site that he was in the hospital due to a fall during the night and has a long history of dizziness. Hospital records are pending.' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:37:28
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 18:36:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 18:36:52
User entered 'Subject called clinic on 11/10/2020 and reported that he fell during the previous night when he got up to go to the restroom. He reported he is hospitalized and broke some bones.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:36:52
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 23:00:10

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 23:00:10

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 23:00:10



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
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).	(b) (4), (b) (6)	22 Mar 2021 03:56:41
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:31:22
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 'Illness visit not performed' (Site from DM).	Maria Candelario (b) (4) (b) (4)	19 Mar 2021 16:57:15
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)	19 Mar 2021 10:23:57
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)	14 Feb 2021 20:14:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Feb 2021 20:14:45
Data point term sent to Coder	System	14 Feb 2021 20:13:54
User entered 'Nausea'	Maria Candelario (b) (4) (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '5 Nov 2020'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User entered empty.	System	14 Feb 2021 20:12:54



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '5 Feb 2021'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User entered empty.	System	14 Feb 2021 20:12:54

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Feb 2021 20:17:36
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Feb 2021 20:12:54
	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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Folder: Adverse Events

Form: Adverse Events (10)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54



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Folder: Adverse Events

Form: Adverse Events (10)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Feb 2021 20:17:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	14 Feb 2021 20:17:36
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
User entered empty.	(b) (4)	
	System	14 Feb 2021 20:12:54
	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Feb 2021 20:17:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Feb 2021 20:12:54
	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

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Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Feb 2021 20:17:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	14 Feb 2021 20:17:36
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
User entered empty.	(b) (4)	
	System	14 Feb 2021 20:12:54
	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

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Generated On: 10 Jun 2021 08:16:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
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: Data Entry Error	System	14 Feb 2021 20:17:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
User entered '0'	(b) (4)	
	System	14 Feb 2021 20:12:54
	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

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Form: Adverse Events (10)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

US3572134

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

US3572134

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:16:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Feb 2021 20:17:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Feb 2021 20:17:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Maria Candelario (b) (4)	14 Feb 2021 20:17:36
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Feb 2021 20:12:54
User entered empty.	Maria Candelario (b) (4)	14 Feb 2021 20:12:54
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	14 Feb 2021 20:12:54

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User entered '0'	System	14 Feb 2021 20:12:54

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51
User entered '0'	System	14 Feb 2021 20:12:54

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:51

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 18:42:43
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'USA-US091-2020-mRNA-1273-P301000003'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 14:49:08

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia macrocytic, LLT: Macrocytic anemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Apr 2021 20:30:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 20:30:51
Data point term sent to Coder	System	26 Apr 2021 20:29:46
User entered 'Macrocytic Anemia'	Maria Candelario (b) (4) (b) (4)	26 Apr 2021 20:29:35

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Apr 2021 20:29:35

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered '8 Nov 2020'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 20:29:35

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered 'Yes (Y)'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 20:29:35



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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 Apr 2021 00:22:41
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	System	27 Apr 2021 00:22:41
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	27 Apr 2021 00:22:41
User entered empty.	(b) (4)	
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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 Apr 2021 00:22:41
User entered 'Yes (Y)' reason for change: Data Entry Error	System	27 Apr 2021 00:22:41
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	27 Apr 2021 00:22:41
User entered empty.	(b) (4)	
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Apr 2021 20:29:35

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per DM: If Requires inpatient or prolongation of existing Hospitalization is checked, then Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is expected to be recorded. Please review and update data accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 19:23:05
Query 'Per DM: If Requires inpatient or prolongation of existing Hospitalization is checked, then Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is expected to be recorded. Please review and update data accordingly else clarify.' answered with 'information updated' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 14:16:10
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)	29 Apr 2021 08:13:30
User opened query 'Per DM: If Requires inpatient or prolongation of existing Hospitalization is checked, then Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is expected to be recorded. Please review and update data accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:13:27
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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 'Data updated' (Site from System).	Maria Candelario (b) (4)	27 Apr 2021 00:22:52
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		27 Apr 2021 00:22:41
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		27 Apr 2021 00:22:41

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered '1' reason for change: Data Entry Error	System	27 Apr 2021 00:22:41
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 entered '0'	Maria Candelario (b) (4) (b) (4)	27 Apr 2021 00:22:41
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4) (b) (4)	26 Apr 2021 20:29:35

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:36
Signature has been broken.	(b) (4)	
	(u) (4), (b) (6)	29 Apr 2021 14:15:49
User entered '9 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 14:15:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:36
Signature has been broken.	(b) (4)	
	(u) (4), (b) (6)	29 Apr 2021 14:15:49
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 14:15:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered '0'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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 Apr 2021 00:22:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Apr 2021 00:22:41
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	27 Apr 2021 00:22:41
User entered empty.	(b) (4)	
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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 Apr 2021 00:22:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Apr 2021 00:22:41
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	27 Apr 2021 00:22:41
User entered empty.	(b) (4)	
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:16:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	



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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:16:20

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Apr 2021 00:22:41
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Apr 2021 20:29:35
User entered '0'	Maria Candelario (b) (4) (b) (4)	26 Apr 2021 20:29:35

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	27 Apr 2021 00:22:41
	(b) (4)	
User entered '0'	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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	26 Apr 2021 21:01:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	26 Apr 2021 21:01:58
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	26 Apr 2021 21:01:58
User entered empty.	(b) (4)	
	System	26 Apr 2021 20:29:35
	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	26 Apr 2021 20:29:35
	(b) (4)	

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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 00:22:41

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**Folder: Adverse Events**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 20:29:35



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 20:29:35

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:32:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:32:29
Data point term sent to Coder	System	25 Mar 2021 18:32:02
User entered 'diarrhea'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '17 Mar 2021'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Mar 2021 18:32:02
User entered '00:00' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	25 Mar 2021 18:32:02
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Mar 2021 18:31:42
User entered empty.	Jessica Mcdowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Mar 2021 00:00'	System	25 Mar 2021 18:32:02
User entered empty.	System	25 Mar 2021 18:31:42



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	25 Mar 2021 18:32:41
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).	System	25 Mar 2021 18:32:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	25 Mar 2021 18:31:42
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessica McDowell (b) (4)	25 Mar 2021 18:32:41
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	



US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4) (u) (4), (b) (6)	06 Apr 2021 07:00:28
Query 'Per CDM: AE started after First Dose, however 'Relationship to investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:36:07
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 03:35:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 03:35:50
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 06:04:53
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4) (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
Signature has been broken.	(b) (4) (u) (4), (b) (6)	05 Apr 2021 03:35:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 03:35:50
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	25 Mar 2021 18:31:42

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered 'I'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Jessica McDowell (b) (4)	25 Mar 2021 18:31:42

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:16:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	25 Mar 2021 18:31:42
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:31:42

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:31:42

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:31:42

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Spinal pain, LLT: Spinal pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Apr 2021 19:53:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 19:53:47
Data point term sent to Coder	System	07 Apr 2021 19:53:07
User entered 'spinal pain'	Jessica McDowell (b) (4) (b) (4)	07 Apr 2021 19:52:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '1 Dec 2020'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'I'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	



US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
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	07 Apr 2021 19:54:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	07 Apr 2021 19:54:26
User opened query 'Data is required. Please complete.' (Site from System).	Jessica Mcdowell (b) (4)	07 Apr 2021 19:54:26
User entered empty.	(b) (4)	
	System	07 Apr 2021 19:52:30
	Jessica Mcdowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:16:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	07 Apr 2021 19:52:30
	(b) (4)	

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'subject previously had neck surgery. pcp thinks this is related, per subject'	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 08:16:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	07 Apr 2021 19:52:30

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
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)	23 Apr 2021 22:04:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 22:04:06
Data point term sent to Coder	System	23 Apr 2021 22:03:35
User entered 'Nausea'	(b) (4), (b) (6)	23 Apr 2021 22:03:07



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '29 Sep 2020'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '12:00'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User entered '29 Sep 2020 12:00'	System	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:03:07



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '12:00'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User entered '26 Oct 2020 12:00'	System	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:03:07

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07



**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

US3572134

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Related (RELATED)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07



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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'None (NONE)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'l'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '0'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:03:07

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User entered '0'	System	23 Apr 2021 22:03:07



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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:16:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05
User entered '0'	System	23 Apr 2021 22:03:07

**US3572134**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 08:16:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:26:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:16:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:31
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:09:34
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 14:57:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:57:23
DataPoint Verified.	(b) (4), (b) (6)	21 Feb 2021 00:20:28
User closed query 'Per ETRTR: Please add details for Medications dosed for SAE Fall occurred on 09Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:20:26
User closed query 'Per ETRTR: Per SAE Fall page, ConProcedure was performed. Please complete Concomitant procedures folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:20:16
Query 'Per ETRTR: Per SAE Fall page, ConProcedure was performed. Please complete Concomitant procedures folder, thanks.' answered with 'Data updated' (Site from CRA).	Maria Candelario (b) (4) (b) (4)	14 Feb 2021 20:31:22
Query 'Per ETRTR: Please add details for Medications dosed for SAE Fall occurred on 09Nov20, thanks.' answered with 'Data updated' (Site from CRA).	Maria Candelario (b) (4) (b) (4)	14 Feb 2021 20:31:13
User opened query 'Per ETRTR: Per SAE Fall page, ConProcedure was performed. Please complete Concomitant procedures folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:09:52
User opened query 'Per ETRTR: Please add details for Medications dosed for SAE Fall occurred on 09Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:09:03
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:53:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 11:30:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 11:30:54
Data point term sent to Coder	System	05 Apr 2021 02:33:40
User closed query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	05 Apr 2021 02:32:48
Query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated to reflect Excedrin ingredients' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 02:32:48
Data point term sent to Coder	System	05 Apr 2021 02:32:39
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 02:32:14
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 02:32:14
User entered 'EXCEDRIN - acetaminophen, aspirin, caffeine' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 02:32:14
User opened query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	03 Apr 2021 16:38:32

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:41
Data point term sent to Coder	System	23 Sep 2020 23:04:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:03:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:03:39
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' canceled (Site from System).	Coder Import (b) (4)	23 Sep 2020 23:03:38
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	21 Sep 2020 11:51:37
Data point term sent to Coder	System	18 Sep 2020 21:54:20
User entered 'Excedrin'	Jasmine Ali (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 05:27:19
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 19:22:31
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:53:11
User entered 'Headache'	Jasmine Ali (b) (4)	18 Sep 2020 21:54:04
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '2'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'tablet (TABLET)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'as needed (PRN)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

**Start date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:20:38
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	18 Sep 2020 21:54:04
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:20:38
User entered empty.	Jasmine Ali (b) (4)	18 Sep 2020 21:54:04
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
User entered empty.	System	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
User entered empty.	System	18 Sep 2020 21:54:04

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:57:25
User entered empty.	System	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:17:54
Data point term sent to Coder	System	11 Feb 2021 17:17:22
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Pain due to fall'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '1,000'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'other (OTHER)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:20

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'q4H-int, PRN'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '08 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:44:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Contacted subject and stated that they are still taking medication' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 23:31:35
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:17:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:17:10

US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:17:10

US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:17:10



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:41:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:41:54
Data point term sent to Coder	System	11 Feb 2021 17:40:48
User entered 'Norco'	(b) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Pain due to fall'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '5-325'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'other (OTHER)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'q4H-int, PRN'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '08 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:44:52
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Contacted subject and stated that they are still taking medication' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 23:31:22
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:47:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 17:40:43

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:40:43



US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:40:43

US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:40:43

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 04:17:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 04:17:50
Data point term sent to Coder	System	03 Mar 2021 04:17:10
User entered 'Xanax'	Maria Candelario (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'anxiety'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 06:25:42
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	17 Mar 2021 05:43:16
' answered with 'updated' (Site from DM).		
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 05:42:15
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	17 Mar 2021 00:52:24
' (Site from DM).		
User entered 'I'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 05:42:15
User entered 'tablet (TABLET)'	Maria Candelario (b) (4)	03 Mar 2021 04:16:10
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'as needed (PRN)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:16:10
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN Aug 2019' reason for change:	System	03 Mar 2021 04:16:47
Data Entry Error	Maria Candelario (b) (4)	03 Mar 2021 04:16:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered ' Aug 2019' (non-conformant).	System	03 Mar 2021 04:16:10
	Maria Candelario (b) (4)	03 Mar 2021 04:16:10
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered '0'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:16:10
	(b) (4)	



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Mar 2021 04:16:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 04:16:47
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	03 Mar 2021 04:16:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Mar 2021 04:16:10
User entered empty.	System	03 Mar 2021 04:16:10
	Maria Candelario (b) (4)	03 Mar 2021 04:16:10
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:16:10

US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:16:10

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:16:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 14:50:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 14:50:51
Data point term sent to Coder	System	17 Mar 2021 14:50:42
User entered 'KEPPRA' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:50:04
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 14:49:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 04:20:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 04:20:55
Data point term sent to Coder	System	03 Mar 2021 04:20:11
User entered 'Kepra'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:19:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 04:05:35
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	17 Mar 2021 14:50:27
' answered with 'Indication was changed after clarifying information with subject. ' (Site from DM).		
User entered 'Seizures' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:49:42
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 00:52:38
User entered 'Hypoglycemia'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '1500' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:07:44
User entered '500'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'mg (mg)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:19:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:07:44
User entered 'twice daily (BID)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:03:43
User entered 'UN UNK 2016'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:19:11



**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:19:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:19:11
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 16:07:44
User entered '2'	System	03 Mar 2021 04:19:11

US3572134

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 04:19:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 04:19:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 04:23:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 04:23:00
Data point term sent to Coder	System	03 Mar 2021 04:22:13
User entered 'gabapentin' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:56
User entered 'insomnial'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Mar 2021 04:21:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 04:21:56
User entered 'Insomnia' reason for change: Data Entry Error	Maria Candelario (b) (4)	03 Mar 2021 04:21:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Mar 2021 04:21:11
User entered empty.	System	03 Mar 2021 04:21:11
	Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '600'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered 'mg (mg)'	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'as needed (PRN)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Oral (ORAL)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:31:22
User entered empty.	Maria Candelario (b) (4) (b) (4)	03 Mar 2021 04:21:11



US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'UN UNK 2017'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '0'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered empty.	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:51:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	03 Mar 2021 04:21:11
	(b) (4)	

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:21:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:21:11

**US3572134**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 04:21:11



US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:16:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User closed query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedures are recorded in Concomitant Procedures form. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 04:07:00
Query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedures are recorded in Concomitant Procedures form. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:34:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 05:34:09
User opened query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedures are recorded in Concomitant Procedures form. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:16:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:57:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:20:38

US3572134

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:16:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered '08 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:29:59

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'CT (computed tomography) Abdomen Pelvis W'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:29:59

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Maria Candelario (b) (4)	14 Feb 2021 20:52:06
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	11 Feb 2021 18:29:59

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:29:59

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:43
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered '08 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:34:46

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:43
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'CT Head or Brain WO'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:34:46

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:43
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	14 Feb 2021 20:52:31
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:34:46



US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:43
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:34:46

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:47
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered '08 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:40:16

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:47
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'XR Humerus Min 2 V Right DR, XR Forearm 2 V Right DR, XR Shoulder Complete Min 2 V Right DR'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:40:16

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:47
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	14 Feb 2021 20:52:50
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:40:16

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:47
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:40:16

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:51
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User closed query 'Per DM CLR: Please review if this Con Proc was done for AE #9 FALL (08 NOV 2020-08 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	19 Mar 2021 09:45:55
Query 'Per DM CLR: Please review if this Con Proc was done for AE #9 FALL (08 NOV 2020-08 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary.	(b) (4), (b) (6)	12 Mar 2021 22:26:32
' answered with 'Not related to AE' (Site from DM). User opened query 'Per DM CLR: Please review if this Con Proc was done for AE #9 FALL (08 NOV 2020-08 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:06:48
User entered '09 Nov 2020'	(b) (4), (b) (6)	11 Feb 2021 18:42:32

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:51
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'NI Echo Transthoracic Echocardiogram (TTE) 2D'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:42:32

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:51
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 01:52:58
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'subject had a fall on 08NOV20, day prior to this ECHO. Associated with the "Fall" AE. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:40:42
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:12:54
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Maria Candelario (b) (4)	14 Feb 2021 20:53:42
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:42:32



US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:51
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:42:32

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:54
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered '09 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:44:42

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:54
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'NM MYOCARDIAL PERFUSION STRESS MULTI'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:44:42

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:54
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 06:59:00
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'This procedure was performed as a result of the fall that subject incurred the day before, on 08Nov2020. Correct as entered. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:44:50
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:13:51
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	11 Feb 2021 18:44:58
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	11 Feb 2021 18:44:42
User entered 'Medical History (MH)'	(b) (4), (b) (6)	11 Feb 2021 18:44:42

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:54
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty; reason for change Data Entry Error	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:44:58
User entered 'Hypertension'	(b) (4), (b) (6)	11 Feb 2021 18:44:42

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:58
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered '09 Nov 2020'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:46:02

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:58
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Abdomen ultrasound'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:46:02

**US3572134**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:58
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered 'Medical History (MH)'	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:46:02



US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:01:58
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:08:39
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Feb 2021 18:46:02

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Site Address: [Street](#)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered '10/Nov/2020 21:14'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'l'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '12/Nov/2020 14:30'	(b) (4) System	12 Nov 2020 14:30:53

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 16:44:11
User entered 'l'	(b) (4), (b) (6)	12 Nov 2020 14:30:53

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '18/Nov/2020 11:44'	(b) (4) System	18 Nov 2020 16:44:26

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:41:47
User entered 'l'	(b) (4), (b) (6)	18 Nov 2020 16:44:26

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '25/Nov/2020 15:27'	(b) (4) System	25 Nov 2020 20:27:38



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:41:47
User entered 'l'	(b) (4), (b) (6)	25 Nov 2020 20:27:38

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '08/Feb/2021 10:32'	(b) (4) System	08 Feb 2021 15:32:01

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:41:47
User entered 'l'	(b) (4), (b) (6)	08 Feb 2021 15:32:01

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '16/Feb/2021 11:50'	(b) (4) System	16 Feb 2021 17:50:54

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	19 Feb 2021 20:07:07
User entered 'l'	(b) (4), (b) (6)	16 Feb 2021 17:50:54

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '19/Feb/2021 15:07'	(b) (4) System	19 Feb 2021 20:07:59

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:16:20

**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)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 14:55:36
User entered 'l'	(b) (4), (b) (6)	19 Feb 2021 20:07:59

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered '04/Mar/2021 09:55'	(b) (4) System	04 Mar 2021 14:56:19



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:16:20

**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)	27 Apr 2021 14:49:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:31:22
User entered 'l'	(b) (4) (u) (4), (b) (6)	04 Mar 2021 14:56:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19



US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 16:21:12
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered '27/Apr/2021 10:50'	(b) (4) System	27 Apr 2021 14:50:18

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:16:20

**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)	29 Apr 2021 16:21:12
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:08:04
User entered 'I'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 14:50:18

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58



**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:20**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 18:44:08
User entered '9'	System	27 Apr 2021 14:50:18
User entered '8'	System	04 Mar 2021 14:56:19
User entered '7'	System	19 Feb 2021 20:07:59
User entered '6'	System	16 Feb 2021 17:50:54
User entered '5'	System	08 Feb 2021 15:32:01
User entered '4'	System	25 Nov 2020 20:27:38
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

**US3572134**

**Folder: SAE USA-US091-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 08:16:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:41
User entered '29/Apr/2021 14:44'	(b) (4) System	29 Apr 2021 18:44:08

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:16:20

**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.	Milton Haber (b) (4)	30 Apr 2021 16:37:41
User entered 'I'	(b) (4) (u) (4), (b) (6)	29 Apr 2021 18:44:08