

US3682134 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:21:15

All time stamps listed in this document are displayed in GMT

US3682134

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 20:52:51

Generated On: 10 Jun 2021 09:21:15

[Participant ID](#)

US3682134

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

US3682134

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	46
Age Units	YEARS
Age (Derived)	46
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	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Condition	DIABETES MELLITUS, TYPE II
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Condition	GENERALIZED CHRONIC PAIN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Condition	LEFT FOOT OPEN ULCER
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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 (10)

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:00 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:00
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	283 lb
BMI (<i>xxx.x</i>)	44.41674 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:18:23

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:18:23

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 146245

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) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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)	17 SEP 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:00
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	118 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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)	17 SEP 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 15:22
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 14:51 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 14:51

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) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	14:30 (24 HR)
Collection date and time (derived)	17 SEP 2020 14:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:35	17 SEP 2020 14:35
Nasopharyngeal Swab 2	No		

US3682134

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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 09:21:15

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

97.3 °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

17 SEP 2020 15:24

PC Open Date & Time

17 SEP 2020 15:11

PC Close Date & Time

17 SEP 2020 17:41

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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 98.9 °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	17 SEP 2020 18:36
PC Open Date & Time	17 SEP 2020 18:36
PC Close Date & Time	18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

99.1 °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

18 SEP 2020 12:00

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

98.7 °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

19 SEP 2020 14:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

99.0 °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

20 SEP 2020 12:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

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

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

17 SEP 2020 15:25

PC Open Date & Time

17 SEP 2020 15:11

PC Close Date & Time

17 SEP 2020 17:41

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

17 SEP 2020 18:36

PC Open Date & Time

17 SEP 2020 18:36

PC Close Date & Time

18 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

18 SEP 2020 12:01

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

19 SEP 2020 14:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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 ☐

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:26
PC Open Date & Time	17 SEP 2020 15:11
PC Close Date & Time	17 SEP 2020 17:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 18:37
PC Open Date & Time	17 SEP 2020 18:36
PC Close Date & Time	18 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

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)

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

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 ☒

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:44
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 2948

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

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)

60 of 2948

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:25:25

Generated On: 10 Jun 2021 09:21:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:25:25

Generated On: 10 Jun 2021 09:21:15

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)	15 OCT 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 13:12
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	112 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:25:25

Generated On: 10 Jun 2021 09:21:15

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 15:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3682134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:25:25

Generated On: 10 Jun 2021 09:21:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 14:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	14:32 (24 HR)
Collection date and time (derived)	15 OCT 2020 14:32

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	15 OCT 2020 14:15
Nasopharyngeal Swab 2	No		

US3682134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 15:11

PC Open Date & Time

15 OCT 2020 14:59

PC Close Date & Time

15 OCT 2020 17:29

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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 98.7 °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	15 OCT 2020 19:29
PC Open Date & Time	15 OCT 2020 18:24
PC Close Date & Time	16 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 12:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

98.7 °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

17 OCT 2020 12:00

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

99.1 °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

18 OCT 2020 12:00

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 12:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 02:01

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

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.

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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

99.0 °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

21 OCT 2020 12:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

15 OCT 2020 15:12

PC Open Date & Time

15 OCT 2020 14:59

PC Close Date & Time

15 OCT 2020 17:29

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

15 OCT 2020 19:29

PC Open Date & Time

15 OCT 2020 18:24

PC Close Date & Time

16 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

16 OCT 2020 12:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

18 OCT 2020 12:00

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

19 OCT 2020 12:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

21 OCT 2020 02:02

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

21 OCT 2020 12:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 15:12
PC Open Date & Time	15 OCT 2020 14:59
PC Close Date & Time	15 OCT 2020 17:29

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 19:30
PC Open Date & Time	15 OCT 2020 18:24
PC Close Date & Time	16 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

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 ☒

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 12:01
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

98 of 2948

EAB) (1725)

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 12:01
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

100 of 2948

EAB) (1725)

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 12:00
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2948

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:00
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

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 ☒

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 02:02
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

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 ☒

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 12:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:18:22

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:25:08

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:25:26

Generated On: 10 Jun 2021 09:21:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:25:26

Generated On: 10 Jun 2021 09:21:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 13:32
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:25:26

Generated On: 10 Jun 2021 09:21:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:25:26

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 NOV 2020
Collection time (00:00-23:59)	13:23 (24 HR)
Collection date and time (derived)	13 NOV 2020 13:23

US3682134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:25:26

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 09:17:40
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 00:01:56
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 00:01:37
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 00:01:30

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 00:01:23
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 00:01:20
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 08:40:19

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:01:24

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 00:01:26

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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	16 JAN 2021 05:54:58
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 12:45:52
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

30 JAN 2021 00:01:19

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

06 FEB 2021 00:01:39

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

13 FEB 2021 04:18:34

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:01:24

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 08:02:04

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

06 MAR 2021 08:12:17

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 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	13 MAR 2021 00:02:43
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 00:02:36

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 04:43:23

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 00:02:26

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 00:02:24

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:02:22

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

24 APR 2021 00:02:28

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:02:31

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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°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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	27 NOV 2021 00:01
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Patient Cloud Close Date & Time	01 DEC 2021 23:59
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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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°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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Patient Cloud Open Date & Time	15 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Patient Cloud Open Date & Time	12 NOV 2022 00:01
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Patient Cloud Close Date & Time	16 NOV 2022 23:59
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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3682134

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:21:15

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		01 MAR 2021 04:25:49

US3682134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:15:22

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:15:22

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:52:53

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:52:53

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:52:53

Generated On: 10 Jun 2021 09:21:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682134

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:52:53

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 21:26:48

Generated On: 10 Jun 2021 09:21:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 21:26:48

Generated On: 10 Jun 2021 09:21:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:49 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 13:49
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	104 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682134

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 21:26:48

Generated On: 10 Jun 2021 09:21:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3682134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 21:26:48

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

14:36 (24 HR)

Collection date and time (derived)

12 APR 2021 14:36

US3682134

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 21:26:48

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682134

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:15

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"/>

US3682134

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:21:15

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3682134

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3682134

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Date of updated informed consent (*dd MMM yyyy*) 29 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 29 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3682134

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00-23:59)	14:18 (24 HR)
Collection date and time (derived)	29 JAN 2021 14:18

US3682134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	14:20
Collection Date and Time (derived)	29 JAN 2021 14:20

US3682134

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:17:10

Generated On: 10 Jun 2021 09:21:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

AEID	USA-US081-2020-MRNA-1273-P30 1000001
Adverse event	SYNCOPE, WORSENER FROM BASELINE
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)	21 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)	21 SEP 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 type="radio"/> Grade 4 <input checked="" 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)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	24 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

PT WITH HISTORY OF
RECURRENT SYNCOPE. PT WAS
MOWING LAWN AND FAINTED.
NEIGHBORS CALLED 911. PT
ADMITTED INTO THE
HOSPITAL. NO EVIDENCE OF
CARDIOVASCULAR OR
NEUROLOGIC
ABNORMALITIES. VITAL SIGNS
ON ADMISSION: T 101.1 F, HR
139, BP 139/76, O2 SAT 96% ON
ROOM AIR. WHITE BLOOD
COUNT ON ADMISSION WAS
10.46 WITH A NORMAL
DIFFERENTIAL.
SEDIMENTATION RATE WAS
28. EVIDENCE OF INFECTION
IN LEFT FOOT, CONCERN FOR
CELLULITIS AND
OSTEOMYELITIS. TREATED
WITH VANCOMYCIN 2G IV
ONCE AND ZOSYN (DOSE PER
PHARMACY PROTOCOL)
WHILE INPATIENT AND
SWITCHED TO BACTRIM 1 DS
TABLET PO BID FOR 12 DAYS
ON DISCHARGE. IMAGING
INCLUDED X-RAY OF LEFT
FOOT AND MRI OF LEFT FOOT,
BOTH SHOWED EVIDENCE OF
OSTEOMYELITIS AT THE
FOURTH METATARSAL HEAD.
TRANSTHORACIC
ECHOCARDIOGRAM SHOWED
NORMAL CARDIAC FUNCTION.
CT SCAN OF THE HEAD AND
CERVICAL SPINE WITHOUT
CONTRAST SHOWED NO
ABNORMALITIES OTHER THAN
A CONTUSION OF THE SCALP.
COVID-19 RAPID PCR NP SWAB
TEST WAS NEGATIVE ON
21SEP2020.

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

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

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

AEID	
Adverse event	CONCUSSION
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)	24 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)	4 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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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US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

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	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	PT WAS ADMITTED, SAE-SYNCOPE. PT'S DISCHARGE DX, CONCUSSION. PT NOW HAVING HEADACHES.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

AEID

Adverse event

OSTEOMYELITIS OF LEFT FOOT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

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	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	PATIENT ADMITTED TO HOSPITAL WITH SYNCOPE, FOUND TO HAVE EVIDENCE OF CELLULITIS/OSTEOMYELITIS OF LEFT FOOT AND TREATED WITH ANTIBIOTICS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

AEID	
Adverse event	CELLULITIS OF LEFT FOOT
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)	21 SEP 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 checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT ADMITTED TO HOSPITAL WITH SYNCOPE, FOUND TO HAVE EVIDENCE OF CELLULITIS/OSTEOMYELITIS OF LEFT FOOT AND TREATED WITH ANTIBIOTICS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

AEID	USA-US081-2021-MRNA-1273-P30 1000012
Adverse event	DIABETIC KETOACIDOSIS
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)	2 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 MAR 2021
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)	3 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	9 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	7
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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Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 21:10:42

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PT'S PODIATRIST
RECOMMENDED THAT HE
HAVE HIS LEFT FOOT
EVALUATED AT THE
HOSPITAL, THOUGH HE DENIED
NEW SYMPTOMS. PT SAID
THAT HE WAS HOSPITALIZED
FROM 3/3/21 TO 3/4/21. PT SAID
THAT HE HAD AN MRI OF THE
LEFT FOOT, WHICH WAS
NEGATIVE. PT SAID THAT HE IS
TAKING CIPROFLOXACIN BID,
FOLLOWING THIS VISIT.

HOSPITAL MEDICAL RECORDS
WERE RECEIVED ON 3/22/21.
THE PT WAS HOSPITALIZED
FROM 3/2/21 TO 3/9/21 FOR DKA,
IN ADDITION TO NECROTIZING
FASCIITIS AND
OSTEOMYELITIS OF THE LEFT
FOOT. VITAL SIGNS ON
ADMISSION: ORAL
TEMPERATURE OF 99.4
DEGREES F, BP OF 123/74, HR OF
130, SPO2 OF 100%. THE PT HAD
AN ANGIOPLASTY OF THE LEFT
LOWER EXTREMITY ON
22FEB2021 AS AN OUTPATIENT
PRIOR TO THIS
HOSPITALIZATION.
DIAGNOSTICS INCLUDED AN
MRI OF THE LEFT FOOT AND
ANKLE, XR OF LEFT FOOT AND

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ANKLE, XR OF CHEST, XR OF TIBIA/FIBULA, ULTRASOUND OF THE BILATERAL LOWER EXTREMITIES, ELECTROCARDIOGRAM, LEFT FOOT WOUND CULTURES, BLOOD CULTURES, CHEMISTRY PANELS, AND URINALYSIS. ON 04MAR2021, THE PT HAD A STAGED DEEP INCISION AND DRAINAGE WITH FASCIOTOMY THROUGH MULTIPLE LAYERS WITH EXCISIONAL DEBRIDMENT OF ALL NON-VIABLE TISSUE AND 3RD METATARSAL RESECTION OF LEFT FOOT. FURTHER TREATMENT INCLUDED FLUID MANAGEMENT, ELECTROLYTE REPLACEMENT, INSULIN MANGEMENT, AND ANTIBIOTICS. PT RECEIVED A LEFT PERIPHERALLY INSERTED CENTRAL CATHETER ON 09MAR2021 FOR CONTINUED IV ANTIBIOTIC ADMINISTRATION THROUGH HOME HEALTH SERVICES. DISCHARGE MEDICATIONS INCUED ANCEF IV, AND CIPROFLOXACIN PO.

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)	1

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Data signed: (b) (4) 22 Apr 2021 21:10:42

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AEID	USA-US081-2021-MRNA-1273-P30 1000012
Adverse event	OSTEOMYELITIS OF LEFT FOOT
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)	2 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	3 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	9 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	7
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

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Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 21:10:42

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PT'S PODIATRIST
RECOMMENDED THAT HE
HAVE HIS LEFT FOOT
EVALUATED AT THE
HOSPITAL, THOUGH HE DENIED
NEW SYMPTOMS. PT SAID
THAT HE WAS HOSPITALIZED
FROM 3/3/21 TO 3/4/21. PT SAID
THAT HE HAD AN MRI OF THE
LEFT FOOT, WHICH WAS
NEGATIVE. PT SAID THAT HE IS
TAKING CIPROFLOXACIN BID,
FOLLOWING THIS VISIT.

HOSPITAL MEDICAL RECORDS
WERE RECEIVED ON 3/22/21.

THE PT WAS HOSPITALIZED
FROM 3/2/21 TO 3/9/21 FOR DKA
AND SECONDARY TREATMENT
OF LEFT FOOT OSTEOMYELITIS
AND CELLULITIS.

DIAGNOSTICS INCLUDED AN
MRI OF THE LEFT FOOT AND
ANKLE, XR OF LEFT FOOT AND
ANKLE, XR OF CHEST, XR OF
TIBIA/FIBULA, ULTRASOUND
OF THE BILATERAL LOWER
EXTREMITIES,
ELECTROCARDIOGRAM, LEFT
FOOT WOUND CULTURES,
BLOOD CULTURES,
CHEMISTRY PANELS, AND
URINALYSIS. ON 04MAR2021,
THE PT HAD A STAGED DEEP
INCISION AND DRAINAGE

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WITH FASCIOTOMY THROUGH
MULTIPLE LAYERS WITH
EXCISIONAL DEBRIDMENT OF
ALL NON-VIABLE TISSUE AND
3RD METATARSAL RESECTION
OF LEFT FOOT. FURTHER
TREATMENT INCLUDED FLUID
MANAGEMENT, ELECTROLYTE
REPLACEMENT, INSULIN
MANGEMENT, AND
ANTIBIOTICS. PT RECEIVED A
LEFT PERIPHERALLY INSERTED
CENTRAL CATHETER ON
09MAR2021 FOR CONTINUED IV
ANTIBIOTIC ADMINISTRATION
THROUGH HOME HEALTH
SERVICES. DISCHARGE
MEDICATIONS INCUDED
ANCEF IV, AND
CIPROFLOXACIN PO.

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)	1

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Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 21:10:42

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AEID

Adverse event

NECROTIZING FASCIITIS OF
LEFT FOOT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 21:10:42

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:10:42

Generated On: 10 Jun 2021 09:21:15

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:10:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 20:52:52

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication HUMALOG INSULIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 14

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 1.8.

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 10

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 21:10:43

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Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication TIZANIDINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN - GENERALIZED

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2010	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN - GENERALIZED

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication TRADJENTA

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 21:10:43

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED CHRONIC PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication HEARTBURN PREVENTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES AS A RESULT OF A
CONCUSSION

Dose per administration 1600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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)	24 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)		04 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS/OSTEOMYELITIS
OF LEFT FOOT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 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)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS/OSTEOMYELITIS
OF LEFT FOOT

Dose per administration PER PHARMACY

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

If dose unit is Other, specify DOSING "PER PHARMACY"

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 "PER PHARMACY"

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 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)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication BACTRIM DS
-(SULFAMETHOXAZOLE -
TRIMETHOPRIM)

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS/OSTEOMYELITIS
OF LEFT FOOT

Dose per administration 1600/320

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Transdermal	<input type="checkbox"/>
	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	06 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication REGULAR INSULIN

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 13

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

If dose unit is Other, specify UNITS/HOUR

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 CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		8 MAR 2021
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 (19)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication POTASSIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 20

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

If dose unit is Other, specify MMOL

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		3 MAR 2021
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 (22)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication 0.9% NORMAL SALINE AND 40
MEQ POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 125

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

If dose unit is Other, specify ML/HOUR

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 CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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)	6 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		6 MAR 2021
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"/>

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS OF THE LEFT
FOOT, NECROTIZING FASCIITIS
OF LEFT FOOT

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

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL VASCULAR DISEASE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	
21 SEP 2020	CT OF THE HEAD AND CERVICAL SPINE	Adverse Event	
21 SEP 2020	X-RAY OF THE CHEST, LEFT SHOULDER, LEFT FOOT	Adverse Event	
22 SEP 2020	MRI OF THE LEFT FOOT	Adverse Event	
22 SEP 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
4 MAR 2021	MRI OF LEFT FOOT AND LEFT ANKLE	Adverse Event	
4 MAR 2021	STAGED DEEP INCISION AND DRAINAGE WITH FASCIOTOMY THROUGH MULTIPLE LAYERS WITH EXCISIONAL DEBIDMENT OF ALL NON-VIABLE TISSUE AND 3RD METATARSAL RESECTION, LEFT FOOT.	Adverse Event	
9 MAR 2021	INSERTION OF LEFT PERIPHERALLY INSERTED CENTRAL CATHETER	Adverse Event	
4 MAR 2021	X-RAY OF LEFT FOOT AND LEFT ANKLE	Adverse Event	
2 MAR 2021	X-RAY OF CHEST	Adverse Event	
2 MAR 2021	X-RAY OF LEFT TIBIA/FIBULA	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Data signed: (b) (4) 01 Apr 2021 20:52:52

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 MAR 2021	ULTRASOUND OF BILATERAL LOWER EXTREMITIES	Adverse Event	
2 MAR 2021	ELECTROCARDIOGRAM	Adverse Event	
3 MAR 2021	CONTINUOUS CARDIAC MONITOR	Adverse Event	
22 FEB 2021	ANGIOPLASTY OF LEFT LOWER EXTREMITY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:21:15

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:21:15

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 ☐

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	28/SEP/2020 08:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	28/SEP/2020 15:35
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	07/OCT/2020 19:16
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	13/OCT/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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	18/OCT/2020 15:38
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	21/OCT/2020 22:09
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:34
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	17/NOV/2020 21:00
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	04/JAN/2021 17:48
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	12/FEB/2021 12:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/MAR/2021 10:55
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

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Data signed: (b) (4) 08 Apr 2021 18:02:27

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2020-MRNA-1273-P301000001
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	05/APR/2021 09:56
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

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/MAR/2021 07:22
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

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:58
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

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/MAR/2021 12:00
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

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/MAR/2021 15:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/APR/2021 09:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 21:10:43

Generated On: 10 Jun 2021 09:21:15

SAEID	USA-US081-2021-MRNA-1273-P301000012
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/APR/2021 10:58
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

US3682134 (Prod: UCLA Vine Street Clinic - (CRS))

US3682134

Form: Participant Creation

Generated On: 10 Jun 2021 09:21:15

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'US3682134'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 20:54:08

US3682134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 21:25:14

US3682134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 20:54:10

US3682134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Clinic (Clinic)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 21:25:14

US3682134

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'SCRN'	System	17 Sep 2020 21:25:14

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered (b) (6) 1973'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 20:54:11

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '46'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'YEARS'	System	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '46'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Male (M)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jesse Clark (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:27:56
	(b) (4)	

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:27:56
	(b) (4)	

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'I'	Jesse Clark (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User closed query 'Per CDM: Please clarify subject's Race, as HISPANIC is an ethnicity.' (Site from DM).	(b) (4)	28 Sep 2020 11:02:02
Query 'Per CDM: Please clarify subject's Race, as HISPANIC is an ethnicity.' answered with 'patient stated race as "Hispanic" under "other option"' (Site from DM).	Oladunni Adeyiga (b) (4)	23 Sep 2020 23:30:32
User opened query 'Per CDM: Please clarify subject's Race, as HISPANIC is an ethnicity.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:21:47
User entered 'Hispanic'	Jesse Clark (b) (4)	17 Sep 2020 21:27:56
	(b) (4)	

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:27:56
	(b) (4)	

US3682134

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:27:56
	(b) (4)	

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '17 Sep 2020'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Sep 2020'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2020'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 21:28:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 21:28:19
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Jesse Clark (b) (4)	17 Sep 2020 21:28:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 21:28:08
User entered empty.	System	17 Sep 2020 21:28:08
	Jesse Clark (b) (4)	17 Sep 2020 21:28:08
	(b) (4)	

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 21:28:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 21:28:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Jesse Clark (b) (4)	17 Sep 2020 21:28:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 21:28:08
User entered empty.	System	17 Sep 2020 21:28:08
	Jesse Clark (b) (4)	17 Sep 2020 21:28:08
	(b) (4)	

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:28:08
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 20:54:10

US3682134

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'I'	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:28:26
	Jesse Clark (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:21:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:28:32
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:38:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:38:40
Data point term sent to Coder	System	17 Sep 2020 21:37:48
User entered 'Hypertension'	Jesse Clark (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2011'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:37:18
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2011'	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2011'	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:38:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:38:40
Data point term sent to Coder	System	17 Sep 2020 21:37:48
User entered 'Diabetes Mellitus, Type II'	Jesse Clark (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2008'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:37:37
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:37:37
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:37:37
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2008'	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2008'	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:39:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:39:41
Data point term sent to Coder	System	17 Sep 2020 21:38:49
User entered 'Hyperlipidemia'	Jesse Clark (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2015'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:37:53
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2015'	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2015'	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:53

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:37:53

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:46:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:46:24
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of CHRONIC PAIN (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Oct 2020 03:55:44
' (Site from DM).		
Data point term sent to Coder	System	28 Oct 2020 17:53:00
Query 'Per DM CLR: Please update the condition to include the type and/or location of CHRONIC PAIN (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Jesse Clark (b) (4)	28 Oct 2020 17:52:40
' answered with 'Updated to reflect pain is generalized.' (Site from DM).	(b) (4)	
Coding entries removed.	Jesse Clark (b) (4)	28 Oct 2020 17:52:31
User entered 'Generalized CHRONIC PAIN' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of CHRONIC PAIN (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Jesse Clark (b) (4)	28 Oct 2020 17:52:31
' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 08:14:49

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:39:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:39:41
Data point term sent to Coder	System	17 Sep 2020 21:38:50
User entered 'Chronic Pain'	Jesse Clark (b) (4)	17 Sep 2020 21:38:05
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'UN UNK 2008' reason for change:	(b) (4)	
Data Entry Error	Jesse Clark (b) (4)	23 Nov 2020 20:33:03
User entered 'un UNK 2010'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:38:05
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:38:05
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:38:05
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:38:05
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2008'	System	23 Nov 2020 20:33:03
User entered 'Jan 2010'	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2008'	System	23 Nov 2020 20:33:03
User entered '2010'	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous tissue ulcerations, PT: Skin ulcer, LLT: Foot ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:02:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:02:52
Data point term sent to Coder	System	17 Sep 2020 21:38:49
User entered 'Left foot open ulcer'	Jesse Clark (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un Mar 2019'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:38:37
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:38:37
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:38:37
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Mar 2019'	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2019'	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:29
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:48:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:38:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Leg amputation, LLT: Below knee amputation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:31:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:31:42
Data point term sent to Coder	System	17 Sep 2020 21:39:52
User entered 'Right below knee amputation'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2010'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:39:00
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2010'	Jesse Clark (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 06:34:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 06:34:42
Data point term sent to Coder	System	25 Sep 2020 20:09:10
User entered 'Recurrent syncope'	Jesse Clark (b) (4)	25 Sep 2020 20:08:12
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2018'	Jesse Clark (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	25 Sep 2020 20:08:12
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	25 Sep 2020 20:08:12
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	25 Sep 2020 20:08:12
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2018'	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2018'	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
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)	28 Sep 2020 20:20:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 20:20:47
Data point term sent to Coder	System	28 Sep 2020 20:19:09
User entered 'Obesity'	Susan Reed (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'I'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal infection, LLT: Infection MRSA - version MedDRA\23.0.	Coder Import (b) (4)	26 Nov 2020 07:32:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Nov 2020 07:32:04
Data point term sent to Coder	System	25 Nov 2020 22:28:13
User closed query 'CDM Coding: Please split and report each term separately on a separate page to capture coding of all reported terms. Example: 1) MRSA INFECTION OF RIGHT LOWER EXTREMITY LEADING TO BELOW KNEE AMPUTATION 2) BELOW KNEE AMPUTATION' (Site from System).	System	25 Nov 2020 22:28:05
Query 'CDM Coding: Please split and report each term separately on a separate page to capture coding of all reported terms. Example: 1) MRSA INFECTION OF RIGHT LOWER EXTREMITY LEADING TO BELOW KNEE AMPUTATION 2) BELOW KNEE AMPUTATION' answered with 'Events separated for coding purposes, per query resolution.' (Site from System).	Mitchell Stern (b) (4)	25 Nov 2020 22:28:05
User entered 'MRSA INFECTION OF RIGHT LOWER EXTREMITY' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	25 Nov 2020 22:27:35
User opened query 'CDM Coding: Please split and report each term separately on a separate page to capture coding of all reported terms. Example: 1) MRSA INFECTION OF RIGHT LOWER EXTREMITY LEADING TO BELOW KNEE AMPUTATION 2) BELOW KNEE AMPUTATION' (Site from System).	Coder Import (b) (4)	25 Nov 2020 04:45:02
Data point term sent to Coder	System	15 Oct 2020 20:48:08
User entered 'MRSA INFECTION of Right Lower Extremity leading to Below Knee Amputation'	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:48:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'un UNK 2010' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:48:31
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2010'	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2010'	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'Jan 2010'	System	15 Oct 2020 20:48:31
User entered empty.	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '2010'	System	15 Oct 2020 20:48:31
User entered empty.	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 21:44:28
	Jesse Clark (b) (4)	
	(b) (4)	

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '17 Sep 2020'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '14:00'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '17 Sep 2020 14:00'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '67' in	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:44:28
	(b) (4)	
DataPoint set to visible.	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '283' lb	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:44:28
	(b) (4)	
DataPoint set to visible.	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User closed query 'Per CDM Re-Query: Thank you for confirming data is correct. Please confirm if Obesity should be added to Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:43:04
Query 'Per CDM Re-Query: Thank you for confirming data is correct. Please confirm if Obesity should be added to Medical History. Thank you' answered with 'data entered' (Site from DM).	Susan Reed (b) (4)	28 Sep 2020 20:16:08
User opened query 'Per CDM Re-Query: Thank you for confirming data is correct. Please confirm if Obesity should be added to Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 02:52:53
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 02:51:37
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'Data is correct' (Site from DM).	Oladunni Adeyiga (b) (4)	23 Sep 2020 23:33:07
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:37:14
User entered '44.41674'	System	17 Sep 2020 21:44:28
DataPoint set to visible.	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'kg/m2'	System	17 Sep 2020 21:44:28
DataPoint set to visible.	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered missing code ND - Not Done.	(b) (4) Jesse Clark (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered missing code ND - Not Done.	(b) (4) Jesse Clark (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'bpm'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered missing code ND - Not Done.	(b) (4) Jesse Clark (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'breaths/min'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered missing code ND - Not Done.	(b) (4) Jesse Clark (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'mmHg'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered missing code ND - Not Done.	(b) (4) Jesse Clark (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'mmHg'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08

US3682134

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:28:39
	(b) (4)	

US3682134

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:28:39

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

[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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

[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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:29:09
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:29:09
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'I'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

[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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:29:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:29:09
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	17 Sep 2020 21:29:09
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Clinic (Clinic)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'VISIT1'	System	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '146245'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 22:12:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 22:12:51
User entered 'No (N)' reason for change: Data Entry Error	Sandy MacNicoll (b) (4)	17 Sep 2020 22:12:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 22:10:13
User entered empty.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 22:12:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 22:12:51
User entered 'No (N)' reason for change: Data Entry Error	Sandy MacNicoll (b) (4)	17 Sep 2020 22:12:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 22:10:13
User entered empty.	System	17 Sep 2020 22:10:13
	Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 22:12:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 22:12:51
User entered 'No (N)' reason for change: Data Entry Error	Sandy MacNicoll (b) (4)	17 Sep 2020 22:12:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Sep 2020 22:10:13
	Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:23:38
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'No' (Site from DM).	Simone Riley (b) (4) (b) (4)	08 Dec 2020 19:02:09
User entered 'No (N)'	Simone Riley (b) (4) (b) (4)	08 Dec 2020 19:02:03
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:43:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:28:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:28:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Pre-Dose (PREDOSE)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:00'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '17 Sep 2020 14:00'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '98.4' F	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Oral (Oral)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '118'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'bpm'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '16'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'breaths/min'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '121'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '82'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Post-Dose (POSTDOSE)'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '15:22'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '17 Sep 2020 15:22'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '97.3' F	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Oral (Oral)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '103'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'bpm'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '16'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'breaths/min'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '125'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '87'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:06:40

US3682134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:06:40

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:51'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '17 Sep 2020 14:51'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Left Arm (LEFT ARM)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'ONCE'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:30'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '17 Sep 2020 14:30'	System	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:35'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '17 Sep 2020 14:35'	System	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered empty.	System	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	17 Sep 2020 22:44:27

US3682134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	17 Sep 2020 22:44:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:24:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b1dab737-802f-48d3-a165-fd7d40346999'	System	17 Sep 2020 22:24:27
User entered 'Yes (Y)'	System	17 Sep 2020 22:24:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:24:14', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b1dab737-802f-48d3-a165-fd7d40346999'	System	17 Sep 2020 22:24:27
User entered '97.3'	System	17 Sep 2020 22:24:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:24:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b1dab737-802f-48d3-a165-fd7d40346999'	System	17 Sep 2020 22:24:27
User entered 'No (N)'	System	17 Sep 2020 22:24:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:24:25', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b1dab737-802f-48d3-a165-fd7d40346999'	System	17 Sep 2020 22:24:27
User entered '17 Sep 2020 15:24'	System	17 Sep 2020 22:24:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Sep 2020 15:11'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Sep 2020 17:41'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '94579b41-7013-4029-97c3-b800706fb2de' User entered 'Yes (Y)'	System	18 Sep 2020 01:36:39
	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:29', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '94579b41-7013-4029-97c3-b800706fb2de' User entered '98.9'	System	18 Sep 2020 01:36:39
	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '94579b41-7013-4029-97c3-b800706fb2de'	System	18 Sep 2020 01:36:39
User entered 'No (N)'	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:35', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '94579b41-7013-4029-97c3-b800706fb2de' User entered '17 Sep 2020 18:36'	System	18 Sep 2020 01:36:39
	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Sep 2020 18:36'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 2'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:00:19', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '26283267-7d4b-4738-a0a7-cb92acac495a' User entered 'Yes (Y)'	System	18 Sep 2020 19:00:46
	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:00:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '26283267-7d4b-4738-a0a7-cb92acac495a' User entered '99.1'	System	18 Sep 2020 19:00:46
	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:00:39', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '26283267-7d4b-4738-a0a7-cb92acac495a' User entered 'No (N)'	System	18 Sep 2020 19:00:46
	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:00:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '26283267-7d4b-4738-a0a7-cb92acac495a' User entered '18 Sep 2020 12:00'	System	18 Sep 2020 19:00:46
	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 3'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7457d808-345c-4cc4-b13d-9181e9214fd0' User entered 'Yes (Y)'	System	19 Sep 2020 21:44:12
	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:05', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7457d808-345c-4cc4-b13d-9181e9214fd0' User entered '98.7'	System	19 Sep 2020 21:44:12
	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:08', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7457d808-345c-4cc4-b13d-9181e9214fd0'	System	19 Sep 2020 21:44:12
User entered 'No (N)'	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:11', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7457d808-345c-4cc4-b13d-9181e9214fd0'	System	19 Sep 2020 21:44:12
User entered '19 Sep 2020 14:44'	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 4'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:38', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '2d312449-b4f9-41d1-9a4b-83d5caddbdf0' User entered 'Yes (Y)'	System	20 Sep 2020 19:00:58
	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '2d312449-b4f9-41d1-9a4b-83d5caddbdf0' User entered '99.0'	System	20 Sep 2020 19:00:58
	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '2d312449-b4f9-41d1-9a4b-83d5caddbdf0'	System	20 Sep 2020 19:00:58
User entered 'No (N)'	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '2d312449-b4f9-41d1-9a4b-83d5caddbdf0' User entered '20 Sep 2020 12:00'	System	20 Sep 2020 19:00:58
	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 5'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf9d607a-9171-4181-8a2c-f53f08d501f8' User entered 'Yes (Y)'	System	21 Sep 2020 19:00:35
	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf9d607a-9171-4181-8a2c-f53f08d501f8' User entered '98.8'	System	21 Sep 2020 19:00:35
	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf9d607a-9171-4181-8a2c-f53f08d501f8'	System	21 Sep 2020 19:00:35
User entered 'No (N)'	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:28', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf9d607a-9171-4181-8a2c-f53f08d501f8'	System	21 Sep 2020 19:00:35
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 6'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 7'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:24:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4184a6c5-61ba-4a7b-bdae-955c7c71c5b4'	System	17 Sep 2020 22:25:39
User entered 'None (1)'	System	17 Sep 2020 22:25:39

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4184a6c5-61ba-4a7b-bdae-955c7c71c5b4'	System	17 Sep 2020 22:25:39
User entered 'No (N)'	System	17 Sep 2020 22:25:39

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:28', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4184a6c5-61ba-4a7b-bdae-955c7c71c5b4'	System	17 Sep 2020 22:25:39
User entered 'No (N)'	System	17 Sep 2020 22:25:39

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4184a6c5-61ba-4a7b-bdae-955c7c71c5b4'	System	17 Sep 2020 22:25:39
User entered 'None (1)'	System	17 Sep 2020 22:25:39

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4184a6c5-61ba-4a7b-bdae-955c7c71c5b4'	System	17 Sep 2020 22:25:39
User entered '17 Sep 2020 15:25'	System	17 Sep 2020 22:25:39

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 15:11'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 17:41'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf23454b-c261-4106-88a6-a9a3667eabae'	System	18 Sep 2020 01:37:20
User entered 'None (1)'	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf23454b-c261-4106-88a6-a9a3667eabae' User entered 'No (N)'	System	18 Sep 2020 01:37:20
	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf23454b-c261-4106-88a6-a9a3667eabae' User entered 'No (N)'	System	18 Sep 2020 01:37:20
	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf23454b-c261-4106-88a6-a9a3667eabae'	System	18 Sep 2020 01:37:20
User entered 'None (1)'	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:36:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bf23454b-c261-4106-88a6-a9a3667eabae'	System	18 Sep 2020 01:37:20
User entered '17 Sep 2020 18:36'	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 18:36'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 2'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:00:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa'	System	18 Sep 2020 19:01:32
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa'	System	18 Sep 2020 19:01:32
User entered 'No (N)'	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa' User entered 'No (N)'	System	18 Sep 2020 19:01:32
	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa' User entered 'None (1)'	System	18 Sep 2020 19:01:32
	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa' User entered '18 Sep 2020 12:01'	System	18 Sep 2020 19:01:32
	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 3'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cac9'	System	19 Sep 2020 21:43:45
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:35', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cacf9' User entered 'No (N)'	System	19 Sep 2020 21:43:45
	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:38', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cacf9' User entered 'No (N)'	System	19 Sep 2020 21:43:45
	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cac9'	System	19 Sep 2020 21:43:45
User entered 'None (1)'	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cacf9' User entered '19 Sep 2020 14:43'	System	19 Sep 2020 21:43:45
	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 4'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:55', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9b5e8b14-2246-491c-a6f9-74d227f93bf6'	System	20 Sep 2020 19:01:13
User entered 'None (1)'	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:57', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9b5e8b14-2246-491c-a6f9-74d227f93bf6'	System	20 Sep 2020 19:01:13
User entered 'No (N)'	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:00:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9b5e8b14-2246-491c-a6f9-74d227f93bf6' User entered 'No (N)'	System	20 Sep 2020 19:01:13
	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9b5e8b14-2246-491c-a6f9-74d227f93bf6'	System	20 Sep 2020 19:01:13
User entered 'None (1)'	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9b5e8b14-2246-491c-a6f9-74d227f93bf6' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:13
	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 5'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcba79b-b63d-4b5c-8f4d-dad4870375db'	System	21 Sep 2020 19:00:42
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcb79b-b63d-4b5c-8f4d-dad4870375db' User entered 'No (N)'	System	21 Sep 2020 19:00:42
	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcba79b-b63d-4b5c-8f4d-dad4870375db' User entered 'No (N)'	System	21 Sep 2020 19:00:42
	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:39', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcba79b-b63d-4b5c-8f4d-dad4870375db' User entered 'None (1)'	System	21 Sep 2020 19:00:42
	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:41', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcba79b-b63d-4b5c-8f4d-dad4870375db' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 19:00:42
	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 6'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 7'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:54', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:25:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081' User entered 'None (0)'	System	17 Sep 2020 22:26:08
	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:26:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081'	System	17 Sep 2020 22:26:08
User entered 'No (N)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T15:26:04', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '0166cc55-d54e-4d1f-93a1-4128b3eff081'	System	17 Sep 2020 22:26:08
User entered '17 Sep 2020 15:26'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 15:11'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 17:41'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:04', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:06', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:08', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:10', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2' User entered 'None (0)'	System	18 Sep 2020 01:37:41
	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2'	System	18 Sep 2020 01:37:41
User entered 'No (N)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-17T18:37:16', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'fe1cf813-447c-4eab-9c62-6d71f1db0ed2'	System	18 Sep 2020 01:37:41
User entered '17 Sep 2020 18:37'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '17 Sep 2020 18:36'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 2'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:30', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:42', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:44', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'None (0)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered 'No (N)'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831' User entered '18 Sep 2020 12:01'	System	18 Sep 2020 19:01:53
	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 3'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:17', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'None (0)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered 'No (N)'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:28', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee' User entered '19 Sep 2020 14:44'	System	19 Sep 2020 21:44:30
	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 4'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:06', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:08', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:09', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:11', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:14', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:16', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'None (0)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered 'No (N)'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:21', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:26
	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 5'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e'	System	21 Sep 2020 19:01:25
User entered 'No interference with activity (1)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:48', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'None (0)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:52', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'None (0)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:55', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'None (0)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'None (0)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:01:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'None (0)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:01:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered 'No (N)'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:01:04', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 19:01:25
	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 6'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 7'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:03:50

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:20
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:05:09
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:23

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:05:13
User closed query 'This call was made on a different day per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 00:04:54
Query 'This call was made on a different day per source document. Please verify and update accordingly.' answered with 'source is correct' (Site from CRA).	Susan Reed (b) (4) (b) (4)	27 Oct 2020 17:04:41
User opened query 'This call was made on a different day per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:40:29
User entered '25 Sep 2020'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:23

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:05:16
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:23

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:05:19
User entered empty.	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:23

US3682134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:29

US3682134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	25 Sep 2020 20:44:29

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '1 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:15

US3682134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	01 Oct 2020 20:16:15

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '8 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:02

US3682134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	15 Oct 2020 22:05:02

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '15 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Clinic (Clinic)'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'VISIT2'	System	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	15 Oct 2020 22:20:43
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '15 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13:12'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '15 Oct 2020 13:12'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '98.3' F	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '112'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'bpm'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '16'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'breaths/min'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '133'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '79'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '15 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '15:10'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '15 Oct 2020 15:10'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '98.8' F	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '108'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'bpm'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '16'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'breaths/min'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '143'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '85'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:25

US3682134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '15 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:25

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '15 Oct 2020'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:39'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '15 Oct 2020 14:39'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christopher Blades (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'ONCE'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:32'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '15 Oct 2020 14:32'	System	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '14:15'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '15 Oct 2020 14:15'	System	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered empty.	System	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4)	22 Oct 2020 20:33:07

US3682134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	22 Oct 2020 20:33:07

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b2e6f23a-434b-4f06-ba0c-83d4f7ff48cd' User entered 'Yes (Y)'	System	15 Oct 2020 22:11:44
	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b2e6f23a-434b-4f06-ba0c-83d4f7ff48cd' User entered '98.8'	System	15 Oct 2020 22:11:44
	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b2e6f23a-434b-4f06-ba0c-83d4f7ff48cd'	System	15 Oct 2020 22:11:44
User entered 'No (N)'	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'b2e6f23a-434b-4f06-ba0c-83d4f7ff48cd' User entered '15 Oct 2020 15:11'	System	15 Oct 2020 22:11:44
	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 14:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 17:29'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:28', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '35cdd1ce-ec79-4178-8072-c916539c7eec'	System	16 Oct 2020 02:29:48
User entered 'Yes (Y)'	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '35cdd1ce-ec79-4178-8072-c916539c7eec' User entered '98.7'	System	16 Oct 2020 02:29:48
	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:38', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '35cdd1ce-ec79-4178-8072-c916539c7eec'	System	16 Oct 2020 02:29:48
User entered 'No (N)'	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:44', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '35cdd1ce-ec79-4178-8072-c916539c7eec' User entered '15 Oct 2020 19:29'	System	16 Oct 2020 02:29:48
	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 18:24'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 2'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4af3b593-6fba-4c23-9184-735a195133ff' User entered 'Yes (Y)'	System	16 Oct 2020 19:00:37
	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:29', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4af3b593-6fba-4c23-9184-735a195133ff' User entered '98.7'	System	16 Oct 2020 19:00:37
	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4af3b593-6fba-4c23-9184-735a195133ff'	System	16 Oct 2020 19:00:37
User entered 'No (N)'	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4af3b593-6fba-4c23-9184-735a195133ff' User entered '16 Oct 2020 12:00'	System	16 Oct 2020 19:00:37
	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 3'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:00:45', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ddd8256a-3a3f-40df-989c-04b29e5462c9' User entered 'Yes (Y)'	System	17 Oct 2020 19:00:58
	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:00:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ddd8256a-3a3f-40df-989c-04b29e5462c9' User entered '98.7'	System	17 Oct 2020 19:00:58
	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:00:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ddd8256a-3a3f-40df-989c-04b29e5462c9'	System	17 Oct 2020 19:00:58
User entered 'No (N)'	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:00:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ddd8256a-3a3f-40df-989c-04b29e5462c9' User entered '17 Oct 2020 12:00'	System	17 Oct 2020 19:00:58
	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 4'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:13', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4a8a0c6f-4233-4cc0-8fbd-325f3cfa6633'	System	18 Oct 2020 19:00:28
User entered 'Yes (Y)'	System	18 Oct 2020 19:00:28

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4a8a0c6f-4233-4cc0-8fbd-325f3cfa6633' User entered '99.1'	System	18 Oct 2020 19:00:28
	System	18 Oct 2020 19:00:28

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4a8a0c6f-4233-4cc0-8fbd-325f3cfa6633'	System	18 Oct 2020 19:00:28
User entered 'No (N)'	System	18 Oct 2020 19:00:28

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '4a8a0c6f-4233-4cc0-8fbd-325f3cfa6633'	System	18 Oct 2020 19:00:28
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 19:00:28

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 5'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:17', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a4493535-d05b-464b-8cc6-b22de456ed79' User entered 'Yes (Y)'	System	19 Oct 2020 19:00:30
	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a4493535-d05b-464b-8cc6-b22de456ed79' User entered '98.8'	System	19 Oct 2020 19:00:30
	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:25', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a4493535-d05b-464b-8cc6-b22de456ed79'	System	19 Oct 2020 19:00:30
User entered 'No (N)'	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:27', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a4493535-d05b-464b-8cc6-b22de456ed79' User entered '19 Oct 2020 12:00'	System	19 Oct 2020 19:00:30
	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 6'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:41', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18978ba4-5ab8-41f0-a112-57e655acf4dd' User entered 'Yes (Y)'	System	21 Oct 2020 09:01:55
	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18978ba4-5ab8-41f0-a112-57e655acf4dd' User entered '98.8'	System	21 Oct 2020 09:01:55
	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:48', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18978ba4-5ab8-41f0-a112-57e655acf4dd'	System	21 Oct 2020 09:01:55
User entered 'No (N)'	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:54', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18978ba4-5ab8-41f0-a112-57e655acf4dd' User entered '21 Oct 2020 02:01'	System	21 Oct 2020 09:01:55
	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 7'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:14', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a3c2cbfc-13e3-4b5c-9582-850bb9b9d449' User entered 'Yes (Y)'	System	21 Oct 2020 19:00:27
	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:19', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a3c2cbfc-13e3-4b5c-9582-850bb9b9d449' User entered '99.0'	System	21 Oct 2020 19:00:27
	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:21', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a3c2cbfc-13e3-4b5c-9582-850bb9b9d449'	System	21 Oct 2020 19:00:27
User entered 'No (N)'	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a3c2cbfc-13e3-4b5c-9582-850bb9b9d449' User entered '21 Oct 2020 12:00'	System	21 Oct 2020 19:00:27
	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '3e7c6f97-cd46-4505-acb6-9f6ea00e786a'	System	15 Oct 2020 22:12:07
User entered 'None (1)'	System	15 Oct 2020 22:12:07

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '3e7c6f97-cd46-4505-acb6-9f6ea00e786a'	System	15 Oct 2020 22:12:07
User entered 'No (N)'	System	15 Oct 2020 22:12:07

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:11:59', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '3e7c6f97-cd46-4505-acb6-9f6ea00e786a' User entered 'No (N)'	System	15 Oct 2020 22:12:07
	System	15 Oct 2020 22:12:07

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:03', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '3e7c6f97-cd46-4505-acb6-9f6ea00e786a' User entered 'None (1)'	System	15 Oct 2020 22:12:07
	System	15 Oct 2020 22:12:07

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:06', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '3e7c6f97-cd46-4505-acb6-9f6ea00e786a'	System	15 Oct 2020 22:12:07
User entered '15 Oct 2020 15:12'	System	15 Oct 2020 22:12:07

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 14:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 17:29'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:48', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e11e03ff-200a-407c-a07f-7ce5ae963385'	System	16 Oct 2020 02:30:03
User entered 'None (1)'	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e11e03ff-200a-407c-a07f-7ce5ae963385' User entered 'No (N)'	System	16 Oct 2020 02:30:03
	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:52', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e11e03ff-200a-407c-a07f-7ce5ae963385' User entered 'No (N)'	System	16 Oct 2020 02:30:03
	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:55', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e11e03ff-200a-407c-a07f-7ce5ae963385'	System	16 Oct 2020 02:30:03
User entered 'None (1)'	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:29:57', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e11e03ff-200a-407c-a07f-7ce5ae963385' User entered '15 Oct 2020 19:29'	System	16 Oct 2020 02:30:03
	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 18:24'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 2'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd' User entered 'None (1)'	System	16 Oct 2020 19:00:59
	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd' User entered 'No (N)'	System	16 Oct 2020 19:00:59
	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd'	System	16 Oct 2020 19:00:59
User entered 'No (N)'	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:54', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd' User entered 'None (1)'	System	16 Oct 2020 19:00:59
	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd' User entered '16 Oct 2020 12:00'	System	16 Oct 2020 19:00:59
	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 3'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:00:59', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '68a2395d-2c1f-4e3a-accf-29e8949b1e7a'	System	17 Oct 2020 19:01:12
User entered 'None (1)'	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '68a2395d-2c1f-4e3a-accf-29e8949b1e7a' User entered 'No (N)'	System	17 Oct 2020 19:01:12
	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:03', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '68a2395d-2c1f-4e3a-accf-29e8949b1e7a' User entered 'No (N)'	System	17 Oct 2020 19:01:12
	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:05', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '68a2395d-2c1f-4e3a-accf-29e8949b1e7a' User entered 'None (1)'	System	17 Oct 2020 19:01:12
	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:07', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '68a2395d-2c1f-4e3a-accf-29e8949b1e7a' User entered '17 Oct 2020 12:01'	System	17 Oct 2020 19:01:12
	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 4'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:30', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '107c146b-815b-4179-87e2-cbd67f9b1e4f' User entered 'None (1)'	System	18 Oct 2020 19:00:39
	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '107c146b-815b-4179-87e2-cbd67f9b1e4f' User entered 'No (N)'	System	18 Oct 2020 19:00:39
	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:33', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '107c146b-815b-4179-87e2-cbd67f9b1e4f' User entered 'No (N)'	System	18 Oct 2020 19:00:39
	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:35', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '107c146b-815b-4179-87e2-cbd67f9b1e4f'	System	18 Oct 2020 19:00:39
User entered 'None (1)'	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '107c146b-815b-4179-87e2-cbd67f9b1e4f' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 19:00:39
	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 5'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:31', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'f782262c-3631-4492-bb7d-795a78e9d712'	System	19 Oct 2020 19:00:41
User entered 'None (1)'	System	19 Oct 2020 19:00:41

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'f782262c-3631-4492-bb7d-795a78e9d712'	System	19 Oct 2020 19:00:41
User entered 'No (N)'	System	19 Oct 2020 19:00:41

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:35', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'f782262c-3631-4492-bb7d-795a78e9d712'	System	19 Oct 2020 19:00:41
User entered 'No (N)'	System	19 Oct 2020 19:00:41

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'f782262c-3631-4492-bb7d-795a78e9d712'	System	19 Oct 2020 19:00:41
User entered 'None (1)'	System	19 Oct 2020 19:00:41

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:38', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'f782262c-3631-4492-bb7d-795a78e9d712'	System	19 Oct 2020 19:00:41
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 19:00:41

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 6'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:57', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '27dd8093-c03b-4c69-a573-5c7e0f49af72'	System	21 Oct 2020 09:02:08
User entered 'None (1)'	System	21 Oct 2020 09:02:08

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:01:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '27dd8093-c03b-4c69-a573-5c7e0f49af72'	System	21 Oct 2020 09:02:08
User entered 'No (N)'	System	21 Oct 2020 09:02:08

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '27dd8093-c03b-4c69-a573-5c7e0f49af72'	System	21 Oct 2020 09:02:08
User entered 'No (N)'	System	21 Oct 2020 09:02:08

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:01', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '27dd8093-c03b-4c69-a573-5c7e0f49af72'	System	21 Oct 2020 09:02:08
User entered 'None (1)'	System	21 Oct 2020 09:02:08

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:04', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '27dd8093-c03b-4c69-a573-5c7e0f49af72'	System	21 Oct 2020 09:02:08
User entered '21 Oct 2020 02:02'	System	21 Oct 2020 09:02:08

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 7'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:27', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e00ff407-7dab-46f6-bd01-cb389891ba1d'	System	21 Oct 2020 19:00:42
User entered 'None (1)'	System	21 Oct 2020 19:00:42

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:30', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e00ff407-7dab-46f6-bd01-cb389891ba1d'	System	21 Oct 2020 19:00:42
User entered 'No (N)'	System	21 Oct 2020 19:00:42

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e00ff407-7dab-46f6-bd01-cb389891ba1d'	System	21 Oct 2020 19:00:42
User entered 'No (N)'	System	21 Oct 2020 19:00:42

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:33', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e00ff407-7dab-46f6-bd01-cb389891ba1d'	System	21 Oct 2020 19:00:42
User entered 'None (1)'	System	21 Oct 2020 19:00:42

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e00ff407-7dab-46f6-bd01-cb389891ba1d' User entered '21 Oct 2020 12:00'	System	21 Oct 2020 19:00:42
	System	21 Oct 2020 19:00:42

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:21', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:28', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'None (0)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered 'No (N)'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:35', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34' User entered '15 Oct 2020 15:12'	System	15 Oct 2020 22:12:37
	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 14:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 17:29'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:03', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:05', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:07', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:09', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'None (0)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:13', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered 'No (N)'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515' User entered '15 Oct 2020 19:30'	System	16 Oct 2020 02:30:20
	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '15 Oct 2020 18:24'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 2'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:01', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:03', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:05', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:07', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:09', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'None (0)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered 'No (N)'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:14', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 19:01:17
	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 3'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:13', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:17', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'None (0)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered 'No (N)'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79' User entered '17 Oct 2020 12:01'	System	17 Oct 2020 19:01:30
	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 4'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:42', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:44', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'None (0)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered 'No (N)'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 19:00:57
	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 5'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:42', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:44', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:49', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'None (0)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered 'No (N)'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:55', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6' User entered '19 Oct 2020 12:00'	System	19 Oct 2020 19:00:57
	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 6'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:06', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:09', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:10', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:13', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'None (0)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered 'No (N)'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e' User entered '21 Oct 2020 02:02'	System	21 Oct 2020 09:02:22
	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	15 Oct 2020 22:05:45
User entered 'Day 7'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:39', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:41', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:43', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:44', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:46', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'None (0)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:48', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered 'No (N)'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b' User entered '21 Oct 2020 12:00'	System	21 Oct 2020 19:01:05
	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 22:05:45

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 22:05:45

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered '22 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered empty.	Susan Reed (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:18:23
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:31

US3682134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	22 Oct 2020 20:33:31

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '29 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	Susan Reed (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:22

US3682134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	29 Oct 2020 20:44:22

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	Susan Reed (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered '5 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered empty.	Susan Reed (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:09
User entered 'Yes (Y)'	Susan Reed (b) (4)	05 Nov 2020 21:42:19

US3682134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	05 Nov 2020 21:42:19

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13 Nov 2020'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Clinic (Clinic)'	(b) (4) Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'VISIT3'	System	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13 Nov 2020'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13:32'	(b) (4) Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '13 Nov 2020 13:32'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '98.4' F	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered empty.	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '102'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'bpm'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '16'	(b) (4) Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'breaths/min'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '140'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '81'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'mmHg'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:10

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13 Nov 2020'	(b) (4) Christopher Blades (b) (4)	13 Nov 2020 21:37:10

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered '13:23'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered '13 Nov 2020 13:23'	System	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:25:26
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	04 Dec 2020 23:05:20

US3682134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	04 Dec 2020 23:05:20

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered 'Day 64'	System	17 Sep 2020 22:03:50

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-17T09:17:31', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6bfdc1a9-a65b-4abe-862e-4959dd8086d3' User entered 'No (N)'	System	17 Nov 2020 17:17:45
	System	17 Nov 2020 17:17:45

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-17T09:17:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6bfdc1a9-a65b-4abe-862e-4959dd8086d3'	System	17 Nov 2020 17:17:45
User entered 'No (N)'	System	17 Nov 2020 17:17:45

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-17T09:17:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6bfdc1a9-a65b-4abe-862e-4959dd8086d3' User entered '17 Nov 2020 09:17:40'	System	17 Nov 2020 17:17:45
	System	17 Nov 2020 17:17:45

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 22:03:50

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:31:52
Data entry locked.	System	17 Sep 2020 22:03:50
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 22:03:50

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-24T00:01:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '621ceff8-8f35-46dd-9854-817385ce126b'	System	24 Nov 2020 08:01:59
User entered 'No (N)'	System	24 Nov 2020 08:01:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-24T00:01:54', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '621ceff8-8f35-46dd-9854-817385ce126b'	System	24 Nov 2020 08:01:59
User entered 'No (N)'	System	24 Nov 2020 08:01:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-24T00:01:56', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '621ceff8-8f35-46dd-9854-817385ce126b' User entered '24 Nov 2020 00:01:56'	System	24 Nov 2020 08:01:59
	System	24 Nov 2020 08:01:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-28T00:01:31', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '887d13b7-d8a6-4edd-b6f9-ab879545dea6' User entered 'No (N)'	System	28 Nov 2020 08:01:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-28T00:01:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '887d13b7-d8a6-4edd-b6f9-ab879545dea6' User entered 'No (N)'	System	28 Nov 2020 08:01:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-11-28T00:01:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '887d13b7-d8a6-4edd-b6f9-ab879545dea6' User entered '28 Nov 2020 00:01:37'	System	28 Nov 2020 08:01:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-05T00:01:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6b7b0ffd-8d59-4634-9be1-6701ebc80974' User entered 'No (N)'	System	05 Dec 2020 08:01:37
	System	05 Dec 2020 08:01:37

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-05T00:01:25', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6b7b0ffd-8d59-4634-9be1-6701ebc80974'	System	05 Dec 2020 08:01:37
User entered 'No (N)'	System	05 Dec 2020 08:01:37

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-05T00:01:30', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '6b7b0ffd-8d59-4634-9be1-6701ebc80974' User entered '05 Dec 2020 00:01:30'	System	05 Dec 2020 08:01:37
	System	05 Dec 2020 08:01:37

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-12T00:01:16', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ec7ff6c1-0a2e-4d69-ba76-5b4f3cea2a80'	System	12 Dec 2020 08:01:27
User entered 'No (N)'	System	12 Dec 2020 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-12T00:01:19', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ec7ff6c1-0a2e-4d69-ba76-5b4f3cea2a80'	System	12 Dec 2020 08:01:27
User entered 'No (N)'	System	12 Dec 2020 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-12T00:01:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ec7ff6c1-0a2e-4d69-ba76-5b4f3cea2a80' User entered '12 Dec 2020 00:01:23'	System	12 Dec 2020 08:01:27
	System	12 Dec 2020 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-19T00:01:11', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'de8a1de7-f52f-4cf7-b84c-02220f477e1c'	System	19 Dec 2020 08:01:22
User entered 'No (N)'	System	19 Dec 2020 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-19T00:01:14', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'de8a1de7-f52f-4cf7-b84c-02220f477e1c'	System	19 Dec 2020 08:01:22
User entered 'No (N)'	System	19 Dec 2020 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-19T00:01:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'de8a1de7-f52f-4cf7-b84c-02220f477e1c' User entered '19 Dec 2020 00:01:20'	System	19 Dec 2020 08:01:22
	System	19 Dec 2020 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-26T08:40:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '85fc9506-ace8-4820-8d68-147f79da2b89' User entered 'No (N)'	System	26 Dec 2020 16:40:21
	System	26 Dec 2020 16:40:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-26T08:40:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '85fc9506-ace8-4820-8d68-147f79da2b89'	System	26 Dec 2020 16:40:21
User entered 'No (N)'	System	26 Dec 2020 16:40:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-12-26T08:40:19', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '85fc9506-ace8-4820-8d68-147f79da2b89' User entered '26 Dec 2020 08:40:19'	System	26 Dec 2020 16:40:21
	System	26 Dec 2020 16:40:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-02T00:01:16', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '582dd18f-6ec3-4c6e-bc0f-e5d2c265bd28'	System	02 Jan 2021 08:01:27
User entered 'No (N)'	System	02 Jan 2021 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-02T00:01:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '582dd18f-6ec3-4c6e-bc0f-e5d2c265bd28'	System	02 Jan 2021 08:01:27
User entered 'No (N)'	System	02 Jan 2021 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-02T00:01:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '582dd18f-6ec3-4c6e-bc0f-e5d2c265bd28' User entered '02 Jan 2021 00:01:24'	System	02 Jan 2021 08:01:27
	System	02 Jan 2021 08:01:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-09T00:01:21', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '054deef8-e81a-49d3-a99a-2cc39b782021' User entered 'No (N)'	System	09 Jan 2021 08:01:28
	System	09 Jan 2021 08:01:28

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-09T00:01:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '054deef8-e81a-49d3-a99a-2cc39b782021' User entered 'No (N)'	System	09 Jan 2021 08:01:28
	System	09 Jan 2021 08:01:28

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-09T00:01:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '054deef8-e81a-49d3-a99a-2cc39b782021' User entered '09 Jan 2021 00:01:26'	System	09 Jan 2021 08:01:28
	System	09 Jan 2021 08:01:28

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-16T05:54:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '23fe999d-40ec-44b0-812b-ebd52ce8a460'	System	16 Jan 2021 13:55:01
User entered 'No (N)'	System	16 Jan 2021 13:55:01

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-16T05:54:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '23fe999d-40ec-44b0-812b-ebd52ce8a460'	System	16 Jan 2021 13:55:01
User entered 'No (N)'	System	16 Jan 2021 13:55:01

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-16T05:54:58', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '23fe999d-40ec-44b0-812b-ebd52ce8a460' User entered '16 Jan 2021 05:54:58'	System	16 Jan 2021 13:55:01

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-25T12:45:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cb8bcc31-4ba7-4a67-a26b-6dbefb54fedd'	System	25 Jan 2021 20:45:57
User entered 'No (N)'	System	25 Jan 2021 20:45:57

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-25T12:45:50', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cb8bcc31-4ba7-4a67-a26b-6dbefb54fedd'	System	25 Jan 2021 20:45:57
User entered 'No (N)'	System	25 Jan 2021 20:45:57

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-25T12:45:52', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cb8bcc31-4ba7-4a67-a26b-6dbefb54fedd' User entered '25 Jan 2021 12:45:52'	System	25 Jan 2021 20:45:57

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-30T00:01:15', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e3ff5b5e-5c26-4e9b-ba0f-4f3c49af0996'	System	30 Jan 2021 08:01:22
User entered 'No (N)'	System	30 Jan 2021 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-30T00:01:17', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e3ff5b5e-5c26-4e9b-ba0f-4f3c49af0996'	System	30 Jan 2021 08:01:22
User entered 'No (N)'	System	30 Jan 2021 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-01-30T00:01:19', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e3ff5b5e-5c26-4e9b-ba0f-4f3c49af0996'	System	30 Jan 2021 08:01:22
User entered '30 Jan 2021 00:01:19'	System	30 Jan 2021 08:01:22

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-06T00:01:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '40d371bb-a672-49de-b007-faf56cd482a9' User entered 'No (N)'	System	06 Feb 2021 08:01:45
	System	06 Feb 2021 08:01:45

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-06T00:01:36', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '40d371bb-a672-49de-b007-faf56cd482a9' User entered 'No (N)'	System	06 Feb 2021 08:01:45
	System	06 Feb 2021 08:01:45

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-06T00:01:39', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '40d371bb-a672-49de-b007-faf56cd482a9' User entered '06 Feb 2021 00:01:39'	System	06 Feb 2021 08:01:45
	System	06 Feb 2021 08:01:45

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-13T04:18:29', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9dc354c4-9245-4c9d-81be-80bd418b2ebe' User entered 'No (N)'	System	13 Feb 2021 12:18:36
	System	13 Feb 2021 12:18:36

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-13T04:18:31', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9dc354c4-9245-4c9d-81be-80bd418b2ebe' User entered 'No (N)'	System	13 Feb 2021 12:18:36

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-13T04:18:34', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9dc354c4-9245-4c9d-81be-80bd418b2ebe' User entered '13 Feb 2021 04:18:34'	System	13 Feb 2021 12:18:36
	System	13 Feb 2021 12:18:36

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-20T00:01:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'dc8eb5e3-9da8-4dbe-a7b1-232eab09ca25'	System	20 Feb 2021 08:01:26
User entered 'No (N)'	System	20 Feb 2021 08:01:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-20T00:01:20', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'dc8eb5e3-9da8-4dbe-a7b1-232eab09ca25'	System	20 Feb 2021 08:01:26
User entered 'No (N)'	System	20 Feb 2021 08:01:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-20T00:01:24', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'dc8eb5e3-9da8-4dbe-a7b1-232eab09ca25' User entered '20 Feb 2021 00:01:24'	System	20 Feb 2021 08:01:26
	System	20 Feb 2021 08:01:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-27T00:01:57-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9eca4cc0-8c6c-41c8-a494-0c56fb8d76fd' User entered 'No (N)'	System	27 Feb 2021 08:02:07

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-27T00:02:00-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9eca4cc0-8c6c-41c8-a494-0c56fb8d76fd' User entered 'No (N)'	System	27 Feb 2021 08:02:07

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-02-27T00:02:04-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9eca4cc0-8c6c-41c8-a494-0c56fb8d76fd' User entered '27 Feb 2021 08:02:04'	System	27 Feb 2021 08:02:07
	System	27 Feb 2021 08:02:07

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-06T08:12:11-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '12e8d16f-80fa-4521-8220-da2fadbda81e'	System	06 Mar 2021 16:12:21
User entered 'No (N)'	System	06 Mar 2021 16:12:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-06T08:12:15-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '12e8d16f-80fa-4521-8220-da2fadbd81e'	System	06 Mar 2021 16:12:21
User entered 'No (N)'	System	06 Mar 2021 16:12:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-06T08:12:17-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '12e8d16f-80fa-4521-8220-da2fadbd81e'	System	06 Mar 2021 16:12:21
User entered '06 Mar 2021 08:12:17'	System	06 Mar 2021 16:12:21

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:22-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a'	System	13 Mar 2021 08:02:54
User entered 'Yes (Y)'	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:25-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a'	System	13 Mar 2021 08:02:54
User entered 'No (N)'	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:29-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a'	System	13 Mar 2021 08:02:54
User entered 'No (N)'	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:35-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a'	System	13 Mar 2021 08:02:54
User entered 'Yes (Y)'	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Please 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:40-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a'	System	13 Mar 2021 08:02:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-13T00:02:43-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'a0bbb65c-d5ed-4575-9962-77c988f8e25a' User entered '13 Mar 2021 00:02:43'	System	13 Mar 2021 08:02:54
	System	13 Mar 2021 08:02:54

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-20T00:02:31-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '5c4bb992-cee9-4079-b1e2-80b62030124d'	System	20 Mar 2021 07:02:39
User entered 'No (N)'	System	20 Mar 2021 07:02:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-20T00:02:33-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '5c4bb992-cee9-4079-b1e2-80b62030124d'	System	20 Mar 2021 07:02:39
User entered 'No (N)'	System	20 Mar 2021 07:02:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-20T00:02:36-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '5c4bb992-cee9-4079-b1e2-80b62030124d' User entered '20 Mar 2021 00:02:36'	System	20 Mar 2021 07:02:39
	System	20 Mar 2021 07:02:39

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-27T04:43:18-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e4404204-721a-4278-a87f-70ad443a1b4e'	System	27 Mar 2021 11:43:26
User entered 'No (N)'	System	27 Mar 2021 11:43:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-27T04:43:20-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e4404204-721a-4278-a87f-70ad443a1b4e'	System	27 Mar 2021 11:43:26
User entered 'No (N)'	System	27 Mar 2021 11:43:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-27T04:43:23-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'e4404204-721a-4278-a87f-70ad443a1b4e'	System	27 Mar 2021 11:43:26
User entered '27 Mar 2021 04:43:23'	System	27 Mar 2021 11:43:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-03T00:02:20-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'd14ba90c-ccea-433c-8a17-7a4839fc0e96'	System	03 Apr 2021 07:02:30
User entered 'No (N)'	System	03 Apr 2021 07:02:30

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-03T00:02:23-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'd14ba90c-ccea-433c-8a17-7a4839fc0e96'	System	03 Apr 2021 07:02:30
User entered 'No (N)'	System	03 Apr 2021 07:02:30

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-03T00:02:26-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'd14ba90c-ccea-433c-8a17-7a4839fc0e96'	System	03 Apr 2021 07:02:30
User entered '03 Apr 2021 00:02:26'	System	03 Apr 2021 07:02:30

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-10T00:02:19-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '077aaec8-6f60-41e3-9111-78b20b4d0863'	System	10 Apr 2021 07:02:27
User entered 'No (N)'	System	10 Apr 2021 07:02:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-10T00:02:21-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '077aaec8-6f60-41e3-9111-78b20b4d0863'	System	10 Apr 2021 07:02:27
User entered 'No (N)'	System	10 Apr 2021 07:02:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-10T00:02:24-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '077aaec8-6f60-41e3-9111-78b20b4d0863'	System	10 Apr 2021 07:02:27
User entered '10 Apr 2021 00:02:24'	System	10 Apr 2021 07:02:27

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-17T00:02:17-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18ad9b12-f10a-49e1-a7a4-c62379d3b26d' User entered 'No (N)'	System	17 Apr 2021 07:02:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-17T00:02:19-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18ad9b12-f10a-49e1-a7a4-c62379d3b26d' User entered 'No (N)'	System	17 Apr 2021 07:02:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-17T00:02:22-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '18ad9b12-f10a-49e1-a7a4-c62379d3b26d' User entered '17 Apr 2021 00:02:22'	System	17 Apr 2021 07:02:26
	System	17 Apr 2021 07:02:26

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-24T00:02:24-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bb5ca1a8-4b5a-437b-aedd-436b14930200'	System	24 Apr 2021 07:02:31
User entered 'No (N)'	System	24 Apr 2021 07:02:31

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-24T00:02:26-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bb5ca1a8-4b5a-437b-aedd-436b14930200'	System	24 Apr 2021 07:02:31
User entered 'No (N)'	System	24 Apr 2021 07:02:31

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-04-24T00:02:28-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bb5ca1a8-4b5a-437b-aedd-436b14930200'	System	24 Apr 2021 07:02:31
User entered '24 Apr 2021 00:02:28'	System	24 Apr 2021 07:02:31

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-05-01T00:02:26-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '98b649b1-384c-43ff-9e34-edc7b26a7858'	System	01 May 2021 07:02:35
User entered 'No (N)'	System	01 May 2021 07:02:35

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Have you been exposed to someone with 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 (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-05-01T00:02:28-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '98b649b1-384c-43ff-9e34-edc7b26a7858'	System	01 May 2021 07:02:35
User entered 'No (N)'	System	01 May 2021 07:02:35

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-05-01T00:02:31-07:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '98b649b1-384c-43ff-9e34-edc7b26a7858'	System	01 May 2021 07:02:35
User entered '01 May 2021 00:02:31'	System	01 May 2021 07:02:35

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:24:55

US3682134

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:15

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)	25 Apr 2021 18:46:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-01T04:25:44-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'd0bc4512-4f1e-4bd0-a8c7-3e6e5834dd41'	System	01 Mar 2021 12:25:51
User entered 'No (N)'	System	01 Mar 2021 12:25:51

US3682134

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:46:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2021-03-01T04:25:49-08:00', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'd0bc4512-4f1e-4bd0-a8c7-3e6e5834dd41' User entered '01 Mar 2021 04:25:49'	System	01 Mar 2021 12:25:51
	System	01 Mar 2021 12:25:51

US3682134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:15:22
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 20:50:28

US3682134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:15:22
User entered '11 Dec 2020'	Susan Reed (b) (4)	11 Dec 2020 20:50:28

US3682134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:15:22
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	11 Dec 2020 20:50:28

US3682134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:15:22
User entered empty.	Susan Reed (b) (4)	11 Dec 2020 20:50:28

US3682134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:15:22
User entered 'Yes (Y)'	Susan Reed (b) (4)	11 Dec 2020 20:50:33

US3682134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:25:03
User entered 'I'	System	11 Dec 2020 20:50:33

US3682134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 19:26:03

US3682134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '15 Jan 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 19:26:03

US3682134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 19:26:03

US3682134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 19:26:03

US3682134

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 19:26:07

US3682134

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User entered 'I'	System	15 Jan 2021 19:26:07

US3682134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 22:54:15

US3682134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '11 Feb 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 22:54:15

US3682134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 22:54:15

US3682134

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 22:54:15

US3682134

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 22:54:23

US3682134

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User entered 'I'	System	11 Feb 2021 22:54:23

US3682134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 20:48:26

US3682134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '12 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 20:48:26

US3682134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 20:48:26

US3682134

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 20:48:26

US3682134

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	12 Mar 2021 20:48:33

US3682134

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:57:41
User entered 'I'	System	12 Mar 2021 20:48:33

US3682134

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:19

US3682134

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:19

US3682134

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:19

US3682134

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 23:05:19

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '13:49'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 13:49'	System	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '104'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '125'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '76'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 23:05:50

US3682134

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:06:03

US3682134

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:06:03

US3682134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 00:57:10

US3682134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 00:57:10

US3682134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered '14:36'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 00:57:10

US3682134

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 14:36'	System	13 Apr 2021 00:57:10

US3682134

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:26:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:05:08

US3682134

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 23:05:08

US3682134

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:01

US3682134

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:01

US3682134

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[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 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:01

US3682134

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered 'UNBLND_DECIDE'	System	30 Jan 2021 00:14:01

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Simone Riley (b) (4)	04 Feb 2021 18:43:22
User entered '06 Jan 2021'	(b) (4)	
	Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:39:05

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:39:05

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '29 Jan 2021'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	30 Jan 2021 00:24:55

US3682134

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered empty.	System	30 Jan 2021 00:24:55

US3682134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:12

US3682134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:12

US3682134

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '14:18'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:12

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '29 Jan 2021 14:18'	System	30 Jan 2021 00:14:12

US3682134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:30

US3682134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:30

US3682134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '14:20'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:14:30

US3682134

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:08
User entered '29 Jan 2021 14:20'	System	30 Jan 2021 00:14:30

US3682134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:21:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:18
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:17:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:25:55
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:43

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Oct 2020 19:34:59
User entered 'USA-US081-2020-mRNA-1273-P301000001'	System	28 Sep 2020 12:32:49
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 12:32:49

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:11:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 19:21:03
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:21:00
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RECURRENT SYNCOPE. 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)	20 Oct 2020 11:09:57
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:50
Data point term sent to Coder	System	16 Oct 2020 20:20:32
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RECURRENT SYNCOPE. 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 'Episode worse than baseline' (Site from DM).	Jesse Clark (b) (4) (b) (4)	16 Oct 2020 20:20:31
Coding entries removed.	Jesse Clark (b) (4) (b) (4)	16 Oct 2020 20:20:20
User entered 'SYNCOPE, Worsened from baseline' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	16 Oct 2020 20:20:20

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RECURRENT SYNCOPE. 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 Oct 2020 12:29:32
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 21:05:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Sep 2020 21:05:56
Data point term sent to Coder	System	25 Sep 2020 21:05:34
User entered 'Syncope'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:40:33
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:59:38
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'Updated per medical records' (Site from DM).	Mitchell Stern (b) (4)	31 Dec 2020 00:18:51
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	31 Dec 2020 00:18:42
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4)	31 Dec 2020 00:18:42
	(b) (4)	
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:04:33
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:29:57
User entered 'No (N)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:29:59
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:32:25
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:32:28
User entered '21 Sep 2020'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:32:32
User entered empty.	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:35:15
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:40:36
User closed query 'Per DM CLR - RQ: Site's response noted. However, the data was changed again. Please review and verify stop date of this AE as this is episodic and not expected to last for more than 1 day. Review and update eCRF as appropriate. Otherwise, if 24SEP2020 is correct, please confirm and explain. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:39:39
Query 'Per DM CLR - RQ: Site's response noted. However, the data was changed again. Please review and verify stop date of this AE as this is episodic and not expected to last for more than 1 day. Review and update eCRF as appropriate. Otherwise, if 24SEP2020 is correct, please confirm and explain. ' answered with 'End date corrected (end date of 24SEP2021 initially entered to correspond with discharge date for hospitalization in response to syncopal episode).' (Site from DM).	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 22:02:54
DataPoint Un-verified.	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 22:02:50
User entered '21 Sep 2020' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 22:02:50
User opened query 'Per DM CLR - RQ: Site's response noted. However, the data was changed again. Please review and verify stop date of this AE as this is episodic and not expected to last for more than 1 day. Review and update eCRF as appropriate. Otherwise, if 24SEP2020 is correct, please confirm and explain. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:04:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 01:09:11
User closed query 'This end date does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 01:09:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'This end date does not match with source document. Please verify and update accordingly.' answered with 'form updated' (Site from CRA). User entered '24 Sep 2020' reason for change: Per Query Resolution	Susan Reed (b) (4)	16 Nov 2020 23:35:48
User opened query 'This end date does not match with source document. Please verify and update accordingly.' (Site from CRA).	Susan Reed (b) (4)	16 Nov 2020 23:35:23
User closed query 'Per DM CLR: Please review and confirm the end date of this medical condition as this is usually episodic and does not last for more than 1 day. Verify and update stop date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:36:22
Query 'Per DM CLR: Please review and confirm the end date of this medical condition as this is usually episodic and does not last for more than 1 day. Verify and update stop date as appropriate. Otherwise, clarify.' answered with 'End date corrected' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:10:12
User entered '21 Sep 2020' reason for change: Per Query Resolution	Jesse Clark (b) (4)	16 Oct 2020 20:20:42
User opened query 'Per DM CLR: Please review and confirm the end date of this medical condition as this is usually episodic and does not last for more than 1 day. Verify and update stop date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	16 Oct 2020 20:20:20
User entered '24 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 12:29:24
	Susan Reed (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:29
User entered empty.	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:31
User entered 'Grade 4 (Grade 4)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:33
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:35
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:42
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:38
User entered 'I'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:41
User entered '21 Sep 2020'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:46
User entered '24 Sep 2020'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:48
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:51
User entered empty.	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:53
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:54
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:56
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:36:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	28 Sep 2020 18:49:32
User entered 'Related (RELATED)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:37:03
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:37:05
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:40:41
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 19:48:16
User entered '1' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	02 Apr 2021 19:48:16
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 19:47:58
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Mar 2021 21:16:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:16:19
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 21:16:19
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Mar 2021 21:13:48
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 20:21:10
User entered '1' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	16 Oct 2020 20:21:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 20:20:20
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:48:03
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)	20 Oct 2020 11:10:16
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 'Entry corrected.' (Site from DM).	Jesse Clark (b) (4)	16 Oct 2020 20:20:59
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Jesse Clark (b) (4)	16 Oct 2020 20:20:20
	(b) (4)	
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)	15 Oct 2020 12:29:41
User entered '1'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:40:43
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no 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). Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no 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 'Concomitant procedure deselected because all performed procedures for this AE were diagnostic.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:24:02
User entered '0' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	02 Apr 2021 19:50:15
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no 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)	01 Apr 2021 09:25:33
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:13:48
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 21:13:48
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:10
User entered '0'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:48:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:48:16
User entered empty.	Susan Reed (b) (4) (b) (4)	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User closed query 'Per DM CLR: Narrative indicates that the subject had Xray, MRI, Transthoracic Echocardiogram. CT of Head and cervical spine. However, there are not corresponding Concomitant Procedure record that match the information. Please update to record all procedures performed as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Narrative indicates that the subject had Xray, MRI, Transthoracic Echocardiogram. CT of Head and cervical spine. However, there are not corresponding Concomitant Procedure record that match the information. Please update to record all procedures performed as appropriate. Otherwise, clarify.' answered with 'Procedures included to logs. Updated accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 03:26:32
User opened query 'Per DM CLR: Narrative indicates that the subject had Xray, MRI, Transthoracic Echocardiogram. CT of Head and cervical spine. However, there are not corresponding Concomitant Procedure record that match the information. Please update to record all procedures performed as appropriate. Otherwise, clarify.' answered with 'Procedures included to logs. Updated accordingly.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 20:51:11
User opened query 'Per DM CLR: Narrative indicates that the subject had Xray, MRI, Transthoracic Echocardiogram. CT of Head and cervical spine. However, there are not corresponding Concomitant Procedure record that match the information. Please update to record all procedures performed as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:05:54
	(b) (4), (b) (6)	06 Nov 2020 00:56:32
User closed query 'WBC in the Medical report is 10.46. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 00:56:30
Query 'WBC in the Medical report is 10.46. Please verify and update accordingly.' answered with 'form updated' (Site from CRA).	Susan Reed (b) (4) (b) (4)	27 Oct 2020 19:33:13
DataPoint Un-verified.	Susan Reed (b) (4) (b) (4)	27 Oct 2020 19:21:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH HISTORY OF RECURRENT SYNCOPE. PT WAS MOWING LAWN AND FAINTED. NEIGHBORS CALLED 911. PT ADMITTED INTO THE HOSPITAL. NO EVIDENCE OF CARDIOVASCULAR OR NEUROLOGIC ABNORMALITIES. VITAL SIGNS ON ADMISSION: T 101.1 F, HR 139, BP 139/76, O2 SAT 96% ON ROOM AIR. WHITE BLOOD COUNT ON ADMISSION WAS 10.46 WITH A NORMAL DIFFERENTIAL. SEDIMENTATION RATE WAS 28. EVIDENCE OF INFECTION IN LEFT FOOT, CONCERN FOR CELLULITIS AND OSTEOMYELITIS. TREATED WITH VANCOMYCIN 2G IV ONCE AND ZOSYN (DOSE PER PHARMACY PROTOCOL) WHILE INPATIENT AND SWITCHED TO BACTRIM 1 DS TABLET PO BID FOR 12 DAYS ON DISCHARGE. IMAGING INCLUDED X-RAY OF LEFT FOOT AND MRI OF LEFT FOOT, BOTH SHOWED EVIDENCE OF OSTEOMYELITIS AT THE FOURTH METATARSAL HEAD. TRANSTHORACIC ECHOCARDIOGRAM SHOWED NORMAL CARDIAC FUNCTION. CT SCAN OF THE HEAD AND CERVICAL SPINE WITHOUT CONTRAST SHOWED NO ABNORMALITIES OTHER THAN A CONTUSION OF THE SCALP. COVID-19 RAPID PCR NP SWAB TEST WAS NEGATIVE ON 21SEP2020.' reason for change: New Information DataPoint Verified.	Susan Reed (b) (4) (b) (4)	27 Oct 2020 19:21:25
	(b) (4), (b) (6)	27 Oct 2020 17:48:19
User opened query 'WBC in the Medical report is 10.46. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 17:40:00
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 22:08:35

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' answered with 'Records were sent last week, faxed and emailed. Resent (email) today to safety_moderna@iqvia.com' (Site from Safety).	Susan Reed (b) (4)	21 Oct 2020 00:18:03
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 21:08:34
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:27:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:27:07
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:27:00

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:26:54
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. Please leave query open until information is available. ' answered with 'Records from hospitalization submitted as requested.' (Site from Safety).	Jesse Clark (b) (4)	12 Oct 2020 22:34:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available. ' answered with 'Relevant information included.' (Site from Safety).	Jesse Clark (b) (4)	12 Oct 2020 22:32:47
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. Please leave query open until information is available. ' answered with 'Relevant information included.' (Site from Safety).	Jesse Clark (b) (4)	12 Oct 2020 22:32:42

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH HISTORY OF RECURRENT SYNCOPE. PT WAS MOWING LAWN AND FAINTED. NEIGHBORS CALLED 911. PT ADMITTED INTO THE HOSPITAL. NO EVIDENCE OF CARDIOVASCULAR OR NEUROLOGIC ABNORMALITIES. VITAL SIGNS ON ADMISSION: T 101.1 F, HR 139, BP 139/76, O2 SAT 96% ON ROOM AIR. WHITE BLOOD COUNT ON ADMISSION WAS 10.6 WITH A NORMAL DIFFERENTIAL. Sedimentation rate was 28. EVIDENCE OF INFECTION IN LEFT FOOT, CONCERN FOR CELLULITIS AND OSTEOMYELITIS. TREATED WITH VANCOMYCIN 2G IV ONCE AND ZOSYN (DOSE PER PHARMACY PROTOCOL) WHILE INPATIENT AND SWITCHED TO BACTRIM 1 DS TABLET PO BID FOR 12 DAYS ON DISCHARGE. IMAGING INCLUDED X-RAY OF LEFT FOOT AND MRI OF LEFT FOOT, BOTH SHOWED EVIDENCE OF OSTEOMYELITIS AT THE FOURTH METATARSAL HEAD. TRANSTHORACIC ECHOCARDIOGRAM SHOWED NORMAL CARDIAC FUNCTION. CT SCAN OF THE HEAD AND CERVICAL SPINE WITHOUT CONTRAST SHOWED NO ABNORMALITIES OTHER THAN A CONTUSION OF THE SCALP. COVID-19 Rapid PCR NP Swab Test WAS NEGATIVE on 21SEP2020.' reason for change: New Information Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' answered with 'Relevant information included.' (Site from Safety).	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:32:33
	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:30:46

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH HISTORY OF RECURRENT SYNCOPE. PT WAS MOWING LAWN AND FAINTED. NEIGHBORS CALLED 911. PT ADMITTED INTO THE HOSPITAL. NO EVIDENCE OF CARDIOVASCULAR OR NEUROLOGIC ABNORMALITIES. Vital signs on admission: T 101.1 F, HR 139, BP 139/76, O2 Sat 96% on room air. White blood count on admission was 10.6 with a normal differential. Evidence of infection in Left foot, concern for cellulitis and osteomyelitis. Treated with Vancomycin 2g IV once and Zosyn (dose per pharmacy protocol) while inpatient and switched to Bactrim 1 DS tablet PO BID for 12 days on discharge. Imaging included x-ray of left foot and MRI of left foot, both showed evidence of osteomyelitis at the fourth metatarsal head. Transthoracic echocardiogram showed normal cardiac function. CT scan of the head and cervical spine without contrast showed no abnormalities other than a contusion of the scalp. COVID-19 PCR was negative.' reason for change: New Information	Jesse Clark (b) (4)	12 Oct 2020 22:30:40
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:22:41
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:22:21

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:21:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:21:10
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)	07 Oct 2020 19:15:53
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:15:50
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)	07 Oct 2020 19:15:47
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)	07 Oct 2020 19:15:44

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
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 'Hospital records requested but not yet available. Information will be provided when available.' (Site from Safety).	Jesse Clark (b) (4)	06 Oct 2020 15:30:12
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 'Hospital records requested but not yet available. Information will be provided when available.' (Site from Safety).	Jesse Clark (b) (4)	06 Oct 2020 15:30:07
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Hospital records requested but not yet available. Information will be provided when available.' (Site from Safety).	Jesse Clark (b) (4)	06 Oct 2020 15:29:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Hospital records requested but not yet available. Information will be provided when available.' (Site from Safety).	Jesse Clark (b) (4)	06 Oct 2020 15:29:55
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)	05 Oct 2020 15:48:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 15:48:27

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
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)	05 Oct 2020 15:48:18
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)	05 Oct 2020 15:48:02
User entered 'PT WITH HISTORY OF RECURRENT SYNCOPE. PT WAS MOWING LAWN AND FAINTED. NEIGHBORS CALLED 911. PT ADMITTED INTO THE HOSPITAL. No evidence of cardiovascular or neurologic abnormalities.' reason for change: New Information	Jesse Clark (b) (4)	28 Sep 2020 19:06:38
User entered 'Pt with history of recurrent syncope. PT WAS MOWING LAWN AND FAINTED. NEIGHBORS CALLED 911. PT ADMITTED INTO THE HOSPITAL.' reason for change: Data Entry Error	Jesse Clark (b) (4)	28 Sep 2020 18:49:32
User entered 'Pt was mowing lawn and fainted. Neighbors called 911. Pt admitted into the hospital.'	Susan Reed (b) (4)	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Dec 2020 00:18:42
User entered '0'	System	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 21:05:31

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:47:24
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:41:50
Data point term sent to Coder	System	01 Oct 2020 20:40:46
User entered 'Concussion'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:47:28
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:27:23
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:27:26
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:33
User entered '24 Sep 2020'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:35
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User entered empty.	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:37
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	08 Oct 2020 20:11:41
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User closed query 'There is no end date in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:43
Query 'There is no end date in source document. Please verify and update accordingly.' answered with 'form updated' (Site from CRA).	Susan Reed (b) (4)	27 Oct 2020 19:32:50
User opened query 'There is no end date in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:39:38
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 20:12:00
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	08 Oct 2020 20:12:00
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	08 Oct 2020 20:11:41
User entered '4 Oct 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	08 Oct 2020 20:11:41
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:48
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User entered empty.	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:36:59
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:02
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:05
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:07
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:10
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:13
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:28
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:30
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:32
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:34
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:38
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:39
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:41
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:43
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:13:32
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:13:34
User entered '1'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:13:36
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:57:26
User closed query 'This is stated as "recovering in source document" please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:57:23
Query 'This is stated as "recovering in source document" please verify and update accordingly.' answered with 'corrected' (Site from CRA).	Susan Reed (b) (4)	07 Nov 2020 00:21:35
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:17:09
User opened query 'This is stated as "recovering in source document" please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:16:55
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:15:30
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:15:24
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:15:22
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:15:19
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Susan Reed (b) (4)	08 Oct 2020 20:12:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:13:39
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:13:41
User entered 'Pt was admitted, SAE-syncope. Pt's discharge dx, concussion. Pt now having headaches.'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User entered '0'	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59
User entered 'I'	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:36:59

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:44:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis of the foot - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:29:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:29:24
Data point term sent to Coder	System	14 Oct 2020 18:53:29
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	14 Oct 2020 18:52:33
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'update complete' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 18:52:33
Data point term sent to Coder	System	14 Oct 2020 18:52:26
User entered 'OSTEOMYELITIS OF LEFT FOOT' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:52:17
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:19:18
Data point term sent to Coder	System	12 Oct 2020 22:37:40
User entered 'Cellulitis/osteomyelitis of left foot'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:44:15
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:44:19
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:44:29
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:44:33
User entered '21 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:54
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User entered empty.	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:40:58
DataPoint Un-verified.	Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:47:12
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Ongoing, pt sees podiatrist weekly.' (Site from DM).	Susan Reed (b) (4)	01 Dec 2020 00:08:10
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:48:56
User entered 'Yes (Y)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:40:59
DataPoint Un-verified.	Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
User entered '06 Oct 2020' reason for change: New Information	(b) (4) Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:02
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:49:13
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User entered empty.	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:49:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:49:34
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:49:36
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:50:52
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:50:55
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:50:57
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:50:59
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:03
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:05
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:07
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:09
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:11
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:13
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:15
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:17
User entered 'None (NONE)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:21
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:51:24
User entered 'I'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:41:04
User closed query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' (Site from DM). Query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' answered with 'Concomitant procedure deselected because all performed procedures for this AE were diagnostic.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:22:19
User entered '0' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	02 Apr 2021 19:51:13
User opened query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:21:41
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:15:30
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 21:15:30
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:28
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:41:05
DataPoint Un-verified.	Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mitchell Stern (b) (4)	11 Feb 2021 22:53:43
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:15:04
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:14:13
Query 'This is not in source document. Please verify and update accordingly.' answered with 'source updated' (Site from CRA).	Susan Reed (b) (4)	27 Oct 2020 22:35:43
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:53:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:53:15
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:53:22
User entered 'Patient admitted to hospital with syncope, found to have evidence of cellulitis/osteomyelitis of left foot and treated with antibiotics.'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User entered '0'	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11
User entered 'I'	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:37:11

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:18:34
User closed query 'This is listed together with Osteomyelitis of the left foot. Please enter them separately and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:18:16
Query 'This is listed together with Osteomyelitis of the left foot. Please enter them separately and update accordingly.' answered with 'source updated' (Site from CRA).	Susan Reed (b) (4)	27 Oct 2020 22:37:07
	(b) (4)	
User opened query 'This is listed together with Osteomyelitis of the left foot. Please enter them separately and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:00:43
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of foot - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 20:28:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 20:28:17
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:53:33
User entered 'CELLULITIS OF LEFT FOOT'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:38
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:43
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:45
User entered '21 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:47
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 07:47:21
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'ongoing, pt sees podiatrist weekly' (Site from DM).	Susan Reed (b) (4) (b) (4)	01 Dec 2020 00:08:33
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:24:28
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:18:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:52
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:18:56
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:27
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:18
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:18:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:29
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		14 Oct 2020 18:54:15
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	14 Oct 2020 18:54:03
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:34
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:35
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:37
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), (b) (6)	15 Oct 2020 15:05:57
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'not related' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 18:55:29
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	14 Oct 2020 18:54:15
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).	System	14 Oct 2020 18:54:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Oct 2020 18:54:15
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:54:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	14 Oct 2020 18:54:03
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	14 Oct 2020 18:54:03

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[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).	System	14 Oct 2020 18:54:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:54:03
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	14 Oct 2020 18:53:32
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:39
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:49
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:56
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:22:58
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:23:00
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:23:02
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:23:03
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:23:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:28:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:28:41
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:28:43
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:02
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:04
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:07
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:10
User entered 'PATIENT ADMITTED TO HOSPITAL WITH SYNCOPE, FOUND TO HAVE EVIDENCE OF CELLULITIS/OSTEOMYELITIS OF LEFT FOOT AND TREATED WITH ANTIBIOTICS.'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:17
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:20:35
User entered	System	15 Mar 2021 14:20:20
'USA-US081-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 14:20:20

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:43:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:08:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:08:41
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 18:08:18
Coding entries removed.	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
	(b) (4)	
User entered 'Diabetic Ketoacidosis' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis of the foot - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 21:20:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 21:20:49
	(b) (4)	
Data point term sent to Coder	System	12 Mar 2021 21:20:29
User entered 'Osteomyelitis of left foot'	Mitchell Stern (b) (4)	12 Mar 2021 21:20:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:25
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:29
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:31
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:40
User entered '2 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:07:27
User entered '3 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	19 Mar 2021 19:25:48
User entered '12 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:43
User entered empty.	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:45
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Mar 2021 18:07:58
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:07:58
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Mar 2021 18:07:27
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:42:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:32:33
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4)	23 Mar 2021 18:09:52
	(b) (4)	
User entered '9 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 12:38:12
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 21:20:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:42:48
User entered empty.	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:02
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	12 Mar 2021 21:20:25
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	12 Mar 2021 21:20:02
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:04
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:06
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:07
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).		12 Mar 2021 21:20:25
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).		12 Mar 2021 21:20:25
User entered '1' reason for change: New Information	Mitchell Stern (b) (4)	12 Mar 2021 21:20:25
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	12 Mar 2021 21:20:02
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:09
User closed query 'PV Query: Please confirm the onset date and/or hospitalization date as currently provided event onset of 12 Mar 2021 with hospitalization of 03 Mar 2021 to 04 Mar2021.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:21:48
Query 'PV Query: Please confirm the onset date and/or hospitalization date as currently provided event onset of 12 Mar 2021 with hospitalization of 03 Mar 2021 to 04 Mar2021.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	19 Mar 2021 19:26:50
User opened query 'PV Query: Please confirm the onset date and/or hospitalization date as currently provided event onset of 12 Mar 2021 with hospitalization of 03 Mar 2021 to 04 Mar2021.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 12:38:59
User entered '3 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:17
User entered '9 Mar 2021' reason for change: Data Entry Error	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
User entered '4 Mar 2021'	(b) (4)	
	Mitchell Stern (b) (4)	12 Mar 2021 21:20:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:18
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:07:27
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:21
User entered '7' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:23
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:27
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:30
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:32
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:34
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:35
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:37
User entered '0'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:38
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:40
User closed query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:25:37
User entered '0' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	02 Apr 2021 19:55:55
Query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' answered with 'Concomitant procedure deselected because all performed procedures for this particular AE were diagnostic.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	02 Apr 2021 19:55:38
User opened query 'Per DM CLR: Treatment Required= Con Proc. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:23:09
User entered '1'	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:43:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:32:37
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4)	23 Mar 2021 18:10:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:07:27
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 12:38:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	12 Mar 2021 21:20:02
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:46
User entered empty.	Mitchell Stern (b) (4) (b) (4)	12 Mar 2021 21:20:02

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:43:48
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 Mar 2021 12:58:54
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 12:58:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT. HOSPITAL MEDICAL RECORDS WERE RECEIVED ON 3/22/21. THE PT WAS HOSPITALIZED FROM 3/2/21 TO 3/9/21 FOR DKA, IN ADDITION TO NECROTIZING FASCIITIS AND OSTEOMYELITIS OF THE LEFT FOOT. VITAL SIGNS ON ADMISSION: ORAL TEMPERATURE OF 99.4 DEGREES F, BP OF 123/74, HR OF 130, SPO2 OF 100%. THE PT HAD AN ANGIOPLASTY OF THE LEFT LOWER EXTREMITY ON 22FEB2021 AS AN OUTPATIENT PRIOR TO THIS HOSPITALIZATION. DIAGNOSTICS INCLUDED AN MRI OF THE LEFT FOOT AND ANKLE, XR OF LEFT FOOT AND ANKLE, XR OF CHEST, XR OF TIBIA/FIBULA, ULTRASOUND OF THE BILATERAL LOWER EXTREMITIES, ELECTROCARDIOGRAM, LEFT FOOT WOUND CULTURES, BLOOD CULTURES, CHEMISTRY PANELS, AND URINALYSIS. ON 04MAR2021, THE PT HAD A STAGED DEEP INCISION AND DRAINAGE WITH FASCIOTOMY THROUGH MULTIPLE LAYERS WITH EXCISIONAL DEBRIDMENT OF ALL NON-VIABLE TISSUE AND 3RD METATARSAL RESECTION OF LEFT FOOT. FURTHER TREATMENT INCLUDED FLUID MANAGEMENT, ELECTROLYTE REPLACEMENT, INSULIN MANGEMENT, AND ANTIBIOTICS. PT RECEIVED A LEFT PERIPHERALLY INSERTED CENTRAL CATHETER ON 09MAR2021 FOR CONTINUED IV ANTIBIOTIC ADMINISTRATION THROUGH HOME HEALTH SERVICES. DISCHARGE	Mitchell Stern (b) (4) (b) (4)	24 Mar 2021 19:54:49

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Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
MEDICATIONS INCLUDED ANCEF IV, AND CIPROFLOXACIN PO.' reason for change: Data Entry Error		
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' answered with 'COVID-19 testing was not mentioned within the labs sections of the medical records.' (Site from Safety).	Mitchell Stern (b) (4)	24 Mar 2021 19:54:22

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT. HOSPITAL MEDICAL RECORDS WERE RECEIVED ON 3/22/21. THE PT WAS HOSPITALIZED FROM 3/2/21 TO 3/9/21 FOR DKA, in addition to necrotizing fasciitis and OSTEOMYELITIS of the left foot. Vital signs on admission: Oral temperature of 99.4 degrees F, BP of 123/74, HR of 130, SpO2 of 100%. The pt had an angioplasty of the left lower extremity on 22FEB2021 as an outpatient prior to this hospitalization. DIAGNOSTICS INCLUDED AN MRI OF THE LEFT FOOT AND ANKLE, XR OF LEFT FOOT AND ANKLE, XR OF CHEST, XR OF TIBIA/FIBULA, ULTRASOUND OF THE BILATERAL LOWER EXTREMITIES, ELECTROCARDIOGRAM, LEFT FOOT WOUND CULTURES, BLOOD CULTURES, CHEMISTRY PANELS, AND URINALYSIS. ON 04MAR2021, THE PT HAD A STAGED DEEP INCISION AND DRAINAGE WITH FASCIOTOMY THROUGH MULTIPLE LAYERS WITH EXCISIONAL DEBRIDMENT OF ALL NON-VIABLE TISSUE AND 3RD METATARSAL RESECTION OF LEFT FOOT. FURTHER TREATMENT INCLUDED FLUID MANAGEMENT, ELECTROLYTE REPLACEMENT, INSULIN MANGEMENT, AND ANTIBIOTICS. PT RECEIVED A LEFT PERIPHERALLY INSERTED CENTRAL CATHETER ON 09MAR2021 FOR CONTINUED IV ANTIBIOTIC ADMINISTRATION THROUGH HOME HEALTH SERVICES. DISCHARGE MEDICATIONS INCUDED ANCEF IV, AND CIPROFLOXACIN PO.' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	24 Mar 2021 19:53:59

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[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 'Procedures from the medical records (02MAR2021 to 09MAR2021) added to the EDC procedure page. Medications from the medical records (02MAR2021 to 09MAR2021) added to the EDC medications page.' (Site from Safety).	Mitchell Stern (b) (4)	24 Mar 2021 19:36:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:32:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Information emailed as requested on 3/23/21' (Site from Safety).	Mitchell Stern (b) (4)	23 Mar 2021 23:21:54

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT. Hospital medical records were received on 3/22/21. The pt was hospitalized from 3/2/21 to 3/9/21 for DKA and secondary treatment of left foot osteomyelitis and cellulitis. Diagnostics included an MRI of the left foot and ankle, XR of left foot and ankle, XR of chest, XR of tibia/fibula, ultrasound of the bilateral lower extremities, electrocardiogram, left foot wound cultures, blood cultures, chemistry panels, and urinalysis. On 04MAR2021, the pt had a staged deep incision and drainage with fasciotomy through multiple layers with excisional debridement of all non-viable tissue and 3rd metatarsal resection of left foot. Further treatment included fluid management, electrolyte replacement, insulin mangement, and antibiotics. Pt received a left peripherally inserted central catheter on 09MAR2021 for continued IV antibiotic administration through home health services. Discharge medications incuded Ancef IV, and Ciprofloxacin PO.' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:03:15
User closed query 'PV Query: Please confirm if ciprofloxacin should be captured as treatment for the event OSTEOMYELITIS OF LEFT FOOT as start date is prior to event (08 Mar 2021) and indication is provided as CELLULITIS OF LEFT FOOT.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:21:53

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if ciprofloxacin should be captured as treatment for the event OSTEOMYELITIS OF LEFT FOOT as start date is prior to event (08 Mar 2021) and indication is provided as CELLULITIS OF LEFT FOOT.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	19 Mar 2021 19:28:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 12:40:06
User opened query 'PV Query: Please confirm if ciprofloxacin should be captured as treatment for the event OSTEOMYELITIS OF LEFT FOOT as start date is prior to event (08 Mar 2021) and indication is provided as CELLULITIS OF LEFT FOOT.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 12:39:24
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) (b) (4)	19 Mar 2021 12:38:43
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 12:37:57

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT.' reason for change: Data Entry Error	Mitchell Stern (b) (4)	12 Mar 2021 21:20:46
User entered 'Pt's podiatrist recommended that the he have his left foot evaluated at the hospital, though he denied new sympoms. Pt said that he was hospitalized from 3/3/21 to 3/4/21. Pt said that he had an MRI of the left foot, which was negative. Pt said that he is taking Ciprofloxacin BID, following this visit.'	Mitchell Stern (b) (4)	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:07:27
User entered '0'	System	12 Mar 2021 21:20:02

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 19:32:47
User entered 'USA-US081-2021-mRNA-1273-P301000012'	(b) (4), (b) (6)	24 Mar 2021 19:05:43

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:44:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis of the foot - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:19:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:19:39
Data point term sent to Coder	System	23 Mar 2021 18:19:36
Coding entries removed.	Mitchell Stern (b) (4)	23 Mar 2021 18:19:11
	(b) (4)	
User entered 'OSTEOMYELITIS of left foot' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:19:11
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:13:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:13:50
Data point term sent to Coder	System	23 Mar 2021 18:13:26
User entered 'Osteomyelitis'	Mitchell Stern (b) (4)	23 Mar 2021 18:12:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:11
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:13
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:15
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:21
User entered '2 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:22
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User closed query 'PV Query: Please provide the event end date for event of OSTEOMYELITIS (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date for event of OSTEOMYELITIS (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated accordingly' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:57:31
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 19:57:31
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 19:57:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:44:24
User opened query 'PV Query: Please provide the event end date for event of OSTEOMYELITIS (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered 'Yes (Y)'	(b) (4), (b) (6) Mitchell Stern (b) (4)	29 Mar 2021 21:11:50 23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 19:57:17
	(b) (4)	
User entered '13 Apr 2021' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 19:57:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:44:26
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 18:12:57
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:28
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:32
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:36
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:37
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:38
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:57
User entered '3 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:44:59
User entered '9 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:01
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:02
User entered '7'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:04
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:06
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:07
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:09
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:10
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:13
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:15
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:17
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User closed query 'PV Query: Please provide the final event outcome for OSTEOMYELITIS, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:57:34
Query 'PV Query: Please provide the final event outcome for OSTEOMYELITIS, when available. Please keep query open until resolution is achieved.' answered with 'Updated accordingly' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 19:57:42
DataPoint Un-verified.	Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 19:57:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 19:57:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:45:19
User opened query 'PV Query: Please provide the final event outcome for OSTEOMYELITIS, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 21:12:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:23
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:44:47
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' answered with 'COVID-19 testing was not included in the medical records received.' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	30 Mar 2021 21:33:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so:' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 21:11:24

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT. HOSPITAL MEDICAL RECORDS WERE RECEIVED ON 3/22/21. THE PT WAS HOSPITALIZED FROM 3/2/21 TO 3/9/21 FOR DKA AND SECONDARY TREATMENT OF LEFT FOOT OSTEOMYELITIS AND CELLULITUS. DIAGNOSTICS INCLUDED AN MRI OF THE LEFT FOOT AND ANKLE, XR OF LEFT FOOT AND ANKLE, XR OF CHEST, XR OF TIBIA/FIBULA, ULTRASOUND OF THE BILATERAL LOWER EXTREMITIES, ELECTROCARDIOGRAM, LEFT FOOT WOUND CULTURES, BLOOD CULTURES, CHEMISTRY PANELS, AND URINALYSIS. ON 04MAR2021, THE PT HAD A STAGED DEEP INCISION AND DRAINAGE WITH FASCIOTOMY THROUGH MULTIPLE LAYERS WITH EXCISIONAL DEBRIDMENT OF ALL NON-VIABLE TISSUE AND 3RD METATARSAL RESECTION OF LEFT FOOT. FURTHER TREATMENT INCLUDED FLUID MANAGEMENT, ELECTROLYTE REPLACEMENT, INSULIN MANGEMENT, AND ANTIBIOTICS. PT RECEIVED A LEFT PERIPHERALLY INSERTED CENTRAL CATHETER ON 09MAR2021 FOR CONTINUED IV ANTIBIOTIC ADMINISTRATION THROUGH HOME HEALTH SERVICES. DISCHARGE MEDICATIONS INCUDED ANCEF IV, AND CIPROFLOXACIN PO.' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:14:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Mar 2021 18:13:58

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Mar 2021 18:13:58
User entered 'PT'S PODIATRIST RECOMMENDED THAT HE HAVE HIS LEFT FOOT EVALUATED AT THE HOSPITAL, THOUGH HE DENIED NEW SYMTPOMS. PT SAID THAT HE WAS HOSPITALIZED FROM 3/3/21 TO 3/4/21. PT SAID THAT HE HAD AN MRI OF THE LEFT FOOT, WHICH WAS NEGATIVE. PT SAID THAT HE IS TAKING CIPROFLOXACIN BID, FOLLOWING THIS VISIT.' reason for change: New Information	Mitchell Stern (b) (4)	23 Mar 2021 18:13:58
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Mar 2021 18:12:57
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:12:57

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Muscle and soft tissue infections, PT: Necrotising fasciitis, LLT: Necrotizing fasciitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 23:14:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 23:14:19
Data point term sent to Coder	System	23 Mar 2021 20:27:52
Coding entries removed.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 20:27:20
User entered 'Necrotizing fasciitis of left foot' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 20:27:20
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of foot - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:20:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:20:39
Data point term sent to Coder	System	23 Mar 2021 18:19:38
Coding entries removed.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:19:23
User entered 'CELLULITIS of left foot' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:19:23
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:18:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:18:39
Data point term sent to Coder	System	23 Mar 2021 18:17:31
User entered 'Cellulitis'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:34
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:36
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:38
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:42
User entered '2 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:44
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:46
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:49
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:51
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:56
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:57
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:45:59
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:00
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:02
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:03
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:06
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:08
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:10
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:12
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:14
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:19
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:21
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:26
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:28
User entered '0'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:29
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated accordingly' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:30:52
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 17:21:02
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 15:10:41
	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:36
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:42
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:44
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:16:36

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:48
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 17:36:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 17:36:11
Data point term sent to Coder	System	31 Mar 2021 17:34:59
User entered 'Peripheral vascular disease'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:50
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:52
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:46:54
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:00
User entered '2 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:02
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:09
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:24
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:26
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:30
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:31
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:35
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:33
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:37
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:39
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:40
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:42
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:44
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:45
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:47
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:50
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:52
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:53
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:55
User entered 'I'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:47:56
User entered '0'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:48:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:48:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:48:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:48:06
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:48:09
User entered empty.	Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 17:34:29

US3682134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 17:34:29

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per ETRTR: Please confirm Medication Dosed for SAE Syncope (or update SAE CRF to indicate no Medication was dosed), thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:45:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:00:59
Query 'Per ETRTR: Please confirm Medication Dosed for SAE Syncope (or update SAE CRF to indicate no Medication was dosed), thanks.' answered with 'Have not received medical records yet.' (Site from CRA).	Susan Reed (b) (4) (b) (4)	29 Sep 2020 18:29:09
User opened query 'Per ETRTR: Please confirm Medication Dosed for SAE Syncope (or update SAE CRF to indicate no Medication was dosed), thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 14:25:31
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:18

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:02:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 06:09:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 06:09:49
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:30:37
User entered 'Humalog insulin'	Jesse Clark (b) (4)	17 Sep 2020 21:30:09
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:06
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:45
User entered 'Diabetes Mellitus Type II'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:48
User entered '14'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:50
User entered 'Other (OTHER)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:53
User entered 'Units'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:56
User entered 'twice daily (BID)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:02:58
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:11
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:15
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:17
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:22
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:25
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:03:28
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:30:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:03:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 04:56:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 04:56:40
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:31:38
User entered 'Victoza'	Jesse Clark (b) (4)	17 Sep 2020 21:30:54
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:09
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:12
User entered 'Diabetes Mellitus Type II'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:50
User entered '1.8.'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:52
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:55
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:57
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:13:58
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:07
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'This is an oral medication - Trulicity' (Site from DM).	Susan Reed (b) (4) (b) (4)	23 Nov 2020 20:27:56
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:51:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:01
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:13
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:19
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:21
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:29
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:33
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:37
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:14:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:32:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:32:42
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:31:38
User entered 'Lantus'	Jesse Clark (b) (4)	17 Sep 2020 21:31:32
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:55
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:14:57
User entered 'Diabetes Mellitus Type II'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:00
User entered '10'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:02
User entered 'Other (OTHER)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:06
User entered 'Units'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:13
User entered 'twice daily (BID)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:15
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:20
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:45
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:47
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:51
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:54
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:15:56
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:31:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:16:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:33:42
Data point term sent to Coder	System	17 Sep 2020 21:32:39
User entered 'Carvedilol'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:07
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:17
User entered 'Hypertension'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:23
User entered '3.125'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:26
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:28
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:31
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:33
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:40
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:48
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:51
User entered 'un UNK 2011'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:53
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:55
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:16:58
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:01
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:32:03

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:33:42
Data point term sent to Coder User entered 'Diltiazem'	System Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:39 17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:23
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:27
User entered 'Hypertension'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:32
User entered '30'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:34
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:36
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:40
User entered 'twice daily (BID)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:42
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:44
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:51
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:55
User entered 'un UNK 2011'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:57
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:59
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:01
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:30
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:32:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:34:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:34:43
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:33:43
User entered 'Metformin'	Jesse Clark (b) (4)	17 Sep 2020 21:33:09
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:40
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:46
User entered 'Diabetes Mellitus Type II'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:50
User entered '1000'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:52
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:54
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:00
User entered 'twice daily (BID)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:01
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:04
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:06
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:11
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:15
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:17
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:20
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:33:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:16:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:16:04
Data point term sent to Coder	System	23 Nov 2020 21:42:47
Coding entries removed.	Susan Reed (b) (4)	23 Nov 2020 21:42:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:34:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:34:44
Data point term sent to Coder	System	17 Sep 2020 21:33:43
User entered 'Tizanidine'	Jesse Clark (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:47
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:50:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 16:36:32
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	Susan Reed (b) (4)	23 Nov 2020 21:42:50
' answered with 'form updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Susan Reed (b) (4)	23 Nov 2020 21:42:42
	(b) (4)	
User entered 'CHRONIC PAIN - generalized' reason for change: Data Entry Error	Susan Reed (b) (4)	23 Nov 2020 21:42:42
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	23 Nov 2020 14:52:41
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:59
User entered 'Chronic pain'	Jesse Clark (b) (4)	17 Sep 2020 21:33:38
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:20:29
User entered '4'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:20:34
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:20:37
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:20:43
User entered 'three times daily (TID)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:20:45
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:32
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:34
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:38
User entered 'un UNK 2010'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:39
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:41
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:43
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:46
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:35:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:35:47
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:34:44
User entered 'Pravastatin'	Jesse Clark (b) (4)	17 Sep 2020 21:34:15
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:21:59
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:10
User entered 'Hyperlipidemia'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:13
User entered '20'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:15
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:17
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:22
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:25
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:42
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:44
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:53
User entered 'un UNK 2015'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:55
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:57
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:00
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:02
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:34:15

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:39:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:39:04
Data point term sent to Coder	System	23 Nov 2020 20:29:18
Coding entries removed.	Susan Reed (b) (4)	23 Nov 2020 20:28:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:36:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:36:48
Data point term sent to Coder	System	17 Sep 2020 21:35:45
User entered 'Amitriptyline'	Jesse Clark (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:19
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:50:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:36:50
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Pt has med hx of generalized chronic pain' (Site from DM).	Susan Reed (b) (4)	23 Nov 2020 20:29:11
	(b) (4)	
DataPoint Un-verified.	Susan Reed (b) (4)	23 Nov 2020 20:28:57
	(b) (4)	
User entered 'CHRONIC PAIN - Generalized' reason for change: Data Entry Error	Susan Reed (b) (4)	23 Nov 2020 20:28:57
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:53:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:26
User entered 'Chronic pain'	Jesse Clark (b) (4)	17 Sep 2020 21:35:13
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:30
User entered '10'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:32
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:34
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:39
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:42
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:51
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:53
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'form updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	23 Nov 2020 21:42:24
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:56:07
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:57
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:59
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:01
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:02
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:04
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:24:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: LINAGLIPTIN, PRODUCTSYNONYM: TRADJENTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:37:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 21:37:39
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 21:36:47
User entered 'Tradjenta'	Jesse Clark (b) (4)	17 Sep 2020 21:35:52
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:12
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:22
User entered 'Diabetes Mellitus Type II'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:50:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:37:45
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'form updated' (Site from DM).	Susan Reed (b) (4)	23 Nov 2020 22:00:09
	(b) (4)	
DataPoint Un-verified.	Susan Reed (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '5' reason for change: Data Entry Error	Susan Reed (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:57:24
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:27
User entered '50'	Jesse Clark (b) (4)	17 Sep 2020 21:35:52
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:24:28
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:03
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:17
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:19
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:23
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:25
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:37
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:39
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:41
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:43
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:31:44
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:35:52

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 23:00:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:00:19
Data point term sent to Coder	System	24 Nov 2020 16:24:30
Coding entries removed.	Mitchell Stern (b) (4)	24 Nov 2020 16:24:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:34:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:37:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:37:39
Data point term sent to Coder	System	17 Sep 2020 21:36:47
User entered 'Tramadol'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:34:30
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:50:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 16:37:55
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	Mitchell Stern (b) (4)	24 Nov 2020 16:24:57
	(b) (4)	
' answered with 'Query resolved. See medical history entry, "generalized chronic pain."' (Site from DM).		
DataPoint Un-verified.	Mitchell Stern (b) (4)	24 Nov 2020 16:24:13
	(b) (4)	
User entered 'Generalized CHRONIC PAIN' reason for change: New Information	Mitchell Stern (b) (4)	24 Nov 2020 16:24:13
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN (e.g. Generalized, Back, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	23 Nov 2020 14:57:54
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:55
User entered 'Chronic Pain'	Jesse Clark (b) (4)	17 Sep 2020 21:36:24
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:34:56
User entered '50'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:34:58
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:07
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:42
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:44
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:51
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:48
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:53
User entered 'un UNK 2010'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:54
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:35:57
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:00
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:02
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:36:24

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 22:29:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:29:00
Data point term sent to Coder	System	24 Nov 2020 17:17:04
Coding entries removed.	Mitchell Stern (b) (4)	24 Nov 2020 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:38:40
Data point term sent to Coder	System	17 Sep 2020 21:37:48
User entered 'Omeprazole'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:11
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:50:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 19:15:43
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' answered with 'query resolved' (Site from DM).	Mitchell Stern (b) (4)	24 Nov 2020 17:17:08
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	24 Nov 2020 17:16:59
	(b) (4)	
User entered 'Heartburn prevention' reason for change: Data Entry Error	Mitchell Stern (b) (4)	24 Nov 2020 17:16:59
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:58:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:18
User entered 'Prophylaxis'	Jesse Clark (b) (4)	17 Sep 2020 21:36:56
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:20
User entered '20'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:22
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:23
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:30
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:32
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:35
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:36
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:41
User entered 'un UNK 2015'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:43
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:45
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:48
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:36:50
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 21:36:56

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 06:32:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 06:32:44
Data point term sent to Coder	System	01 Oct 2020 20:44:02
User entered 'Ibuprofen'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:18
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:37
User entered 'Headaches as a result of a concussion'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:41
User entered '1600'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:43
User entered 'mg (mg)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:45
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:47
User entered 'as needed (PRN)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:49
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:54
User entered 'Oral (ORAL)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:37:51
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:38:11
User entered '24 Sep 2020'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:38:13
User entered '0'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 00:43:12
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:38:21
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:38:14
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4)	08 Oct 2020 20:10:58
User entered 'Yes (Y)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 00:43:14
User closed query 'This date is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 00:43:10
Query 'This date is not in source document. Please verify and update accordingly.' answered with 'source updated' (Site from CRA).	Susan Reed (b) (4)	27 Oct 2020 22:14:15
User opened query 'This date is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:39:02
User entered '04 Oct 2020' reason for change: New Information	Susan Reed (b) (4)	08 Oct 2020 20:10:58
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:39:27
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User entered empty.	System	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User entered empty.	System	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:06
User entered empty.	System	01 Oct 2020 20:43:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:39:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:52:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:52:28
Data point term sent to Coder	System	12 Oct 2020 22:38:43
User entered 'Vancomycin'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:39:42
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:41:40
User entered 'Cellulitis/Osteomyelitis of Left Foot'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:41:50
User entered '2'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:41:55
User entered 'g (g)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:40
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:57
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:43:45
User entered 'once (ONCE)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:43:49
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:43:51
User entered 'Intravenous (INTRAVENOUS)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:43:57
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:43:58
User entered '21 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:44:00
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:44:01
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:44:04
User entered '21 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:44:58
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User entered empty.	System	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User entered empty.	System	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:13
User entered empty.	System	12 Oct 2020 22:38:01

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:45:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 22:41:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 22:41:30
Data point term sent to Coder	System	12 Oct 2020 22:40:47
User entered 'Zosyn'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:45:40
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:45:46
User entered 'Cellulitis/Osteomyelitis of Left Foot'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:45:53
User entered 'Per Pharmacy'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:45:58
User entered 'Other (OTHER)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:29
User entered 'Dosing "Per Pharmacy"'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:35
User entered 'other (OTHER)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:37
User entered "'Per Pharmacy'"	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:39
User entered 'Intravenous (INTRAVENOUS)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:42
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:51
User entered '21 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:11
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:14
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:20
User entered '24 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:26
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User entered empty.	System	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User entered empty.	System	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:21
User entered empty.	System	12 Oct 2020 22:39:57

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 17:45:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	08 Dec 2020 17:45:51
Data point term sent to Coder	System	02 Dec 2020 00:03:50
DataPoint Un-verified.	Susan Reed (b) (4)	02 Dec 2020 00:03:29
Coding entries removed.	(b) (4)	
	Susan Reed (b) (4)	02 Dec 2020 00:03:29
User entered 'BACTRIM DS -(SULFAMETHOXAZOLE - TRIMETHOPRIM)' reason for change: Data Entry Error	(b) (4)	
	Susan Reed (b) (4)	02 Dec 2020 00:03:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:49:41
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 22:41:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 22:41:30
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 22:40:49

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Bactrim'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:49:51
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:49:55
User entered 'Cellulitis/Osteomyelitis of Left Foot'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per DM CLR: Please provide the actual dose instead of # of tablets as there are several dosage options for this combination drug. Please review and update dose and dose unit field to include both doses (e.g., Dose=400/80; Dose Unit=milligram). Please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:05:24
Query 'Per DM CLR: Please provide the actual dose instead of # of tablets as there are several dosage options for this combination drug. Please review and update dose and dose unit field to include both doses (e.g., Dose=400/80; Dose Unit=milligram). Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:03:35
DataPoint Un-verified.	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:03:29
User entered '1600/320' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:03:29
User opened query 'Per DM CLR: Please provide the actual dose instead of # of tablets as there are several dosage options for this combination drug. Please review and update dose and dose unit field to include both doses (e.g., Dose=400/80; Dose Unit=milligram). Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:50:15
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:49:58
User entered '1 DS'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Un-verified.	(b) (4)	
	Susan Reed (b) (4)	02 Dec 2020 00:03:29
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Susan Reed (b) (4)	02 Dec 2020 00:03:29
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:56
User entered 'tablet (TABLET)'	Jesse Clark (b) (4)	12 Oct 2020 22:40:46
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:50:58
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:00
User entered 'twice daily (BID)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:02
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:05
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:08
User entered empty.	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:13
User entered '24 Sep 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:15
User entered '0'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:17
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:21
User entered '06 Oct 2020'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:51:23
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User entered '2'	System	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User entered '1'	System	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:31
User entered '804 (804)'	System	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 05:34:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	08 Apr 2021 05:34:16
Data point term sent to Coder Coding entries removed.	System Mitchell Stern (b) (4)	07 Apr 2021 17:26:12 07 Apr 2021 17:25:24
User signature succeeded.	(b) (4) Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Mar 2021 15:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	22 Mar 2021 15:23:47
Data point term sent to Coder Coding entries removed.	System Mitchell Stern (b) (4)	19 Mar 2021 19:29:23 19 Mar 2021 19:29:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Mar 2021 14:25:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	13 Mar 2021 14:25:39
Data point term sent to Coder	System	12 Mar 2021 20:47:43

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	12 Mar 2021 20:46:43
User entered 'Ciprofloxacin'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:44
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	07 Apr 2021 17:25:24
	(b) (4)	
User entered 'OSTEOMYELITIS OF LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	07 Apr 2021 17:25:24
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Osteomyelitis OF LEFT FOOT' reason for change: New Information	Mitchell Stern (b) (4)	19 Mar 2021 19:29:21
	(b) (4)	
User entered 'CELLULITiS OF LEFT FOOT' reason for change: Data Entry Error	Mitchell Stern (b) (4)	12 Mar 2021 20:46:51
	(b) (4)	
User entered 'Cellulitus of left foot'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '750' reason for change: New Information	Mitchell Stern (b) (4)	12 Mar 2021 21:21:33
	(b) (4)	
User entered '250'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'twice daily (BID)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:51:58
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '8 Mar 2021'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
User entered '7 Apr 2021' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:24:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	12 Mar 2021 20:46:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 20:46:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:46:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 20:46:37

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:55:22
Query 'This is not in source document. Please verify and update accordingly.' answered with 'verified as present and correct per source.' (Site from CRA).	Mitchell Stern (b) (4)	19 Apr 2021 22:59:42
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:07:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:52:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:28:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:28:24
Data point term sent to Coder	System	23 Mar 2021 23:31:10
User entered 'Regular insulin'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:06:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:36
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Diabetic ketoacidosis'	(b) (4) Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '13'	(b) (4)	
	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:06:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:05:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Other (OTHER)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'units/hour'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'other (OTHER)'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'continuous'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:56:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:55:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:55:45
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '8 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:55:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
User entered empty.	System	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
User entered empty.	System	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:37
User entered empty.	System	23 Mar 2021 23:30:36

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:46:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:46:41
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:52:54
Data point term sent to Coder	System	23 Mar 2021 23:32:10
User entered 'Magnesium oxide'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:15
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Diabetic ketoacidosis'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:17
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '400'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mg (mg)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:36
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
User entered empty.	System	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
User entered empty.	System	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:41
User entered empty.	System	23 Mar 2021 23:31:21

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:07:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:05
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:24:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:24:25
Data point term sent to Coder	System	23 Mar 2021 23:32:10
User entered 'Magnesium sulfate'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Diabetic ketoacidosis'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'g (g)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:11:59
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:12:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:12:59
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
User entered empty.	System	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
User entered empty.	System	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:46
User entered empty.	System	23 Mar 2021 23:32:09

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM PHOSPHATE DIBASIC - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 11:48:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 11:48:35
Data point term sent to Coder	System	23 Mar 2021 23:35:12
User entered 'Potassium phosphate'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:17
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Diabetic ketoacidosis'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '20'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Other (OTHER)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mmol'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:13:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:14:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
User entered empty.	System	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
User entered empty.	System	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:50
User entered empty.	System	23 Mar 2021 23:34:11

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:28:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:28:31
Data point term sent to Coder	System	23 Mar 2021 23:38:14
User entered '0.9% Normal saline and 40 meQ potassium chloride'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 23:38:04
User entered 'No (N)' reason for change: Data Entry Error	System	23 Mar 2021 23:38:04
User opened query 'Data is required. Please complete.' (Site from System).	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59
User entered empty.	(b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Diabetic ketoacidosis'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '125'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Other (OTHER)'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:16:58
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'ml/hour'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'other (OTHER)'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'continuous'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:17
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '9 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
User entered empty.	System	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
User entered empty.	System	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:00:55
User entered empty.	System	23 Mar 2021 23:37:59

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:17:59
Data point term sent to Coder	System	07 Apr 2021 17:23:06
Coding entries removed.	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 17:22:39
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:21
Data point term sent to Coder	System	23 Mar 2021 23:40:15
User entered 'Ceftriaxone'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:55
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	07 Apr 2021 17:22:39
	(b) (4)	
User entered 'OSTEOMYELITIS OF LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT'	Mitchell Stern (b) (4)	07 Apr 2021 17:22:39
reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Osteomyelitis of left foot'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:17:58
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'g (g)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:15
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '6 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:24
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '9 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:29
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
User entered '1'	System	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
User entered '1'	System	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:00
User entered '804 (804)'	System	23 Mar 2021 23:39:19

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:08
Data point term sent to Coder	System	07 Apr 2021 17:23:06
Coding entries removed.	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 17:22:55
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:53:53
Data point term sent to Coder	System	23 Mar 2021 23:40:14
User entered 'Clindamycin'	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:37
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:42
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	07 Apr 2021 17:22:55
	(b) (4)	
User entered 'OSTEOMYELITIS OF LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT'	Mitchell Stern (b) (4)	07 Apr 2021 17:22:55
reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Osteomyelitis of left foot'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '450'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'mg (mg)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:18:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'three times daily (TID)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '6 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:19:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:20:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:20:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '9 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:20:36
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
User entered '3'	System	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
User entered '1'	System	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:09
User entered '804 (804)'	System	23 Mar 2021 23:40:08

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:20:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:25:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:25:39
Data point term sent to Coder Coding entries removed.	System Mitchell Stern (b) (4)	07 Apr 2021 17:24:07 07 Apr 2021 17:23:09
User signature succeeded.	(b) (4) Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 23:41:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 23:41:45
Data point term sent to Coder User entered 'Zosyn'	System Mitchell Stern (b) (4)	23 Mar 2021 23:41:15 23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:20:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:03
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
Signature has been broken.	Mitchell Stern (b) (4)	07 Apr 2021 17:23:09
User entered 'OSTEOMYELITIS OF LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	07 Apr 2021 17:23:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Osteomyelitis of left foot'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'unk'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per CDM, re-query: Response noted. Please review "Dose Unit" and "Frequency" and update with either a unit/frequency or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 08:49:20
Query 'Per CDM, re-query: Response noted. Please review "Dose Unit" and "Frequency" and update with either a unit/frequency or "UNK" if unknown. Thank you. ' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	25 Mar 2021 14:33:27
User entered 'Other (OTHER)' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	25 Mar 2021 14:33:09
User opened query 'Per CDM, re-query: Response noted. Please review "Dose Unit" and "Frequency" and update with either a unit/frequency or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:08:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 09:08:01
Query 'Data is required. Please complete.' answered with 'dose unknown, following review of med records.' (Site from System).	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:41:45
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 23:41:06
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 14:33:09
	(b) (4)	
	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Mitchell Stern (b) (4)	25 Mar 2021 14:33:09
Query 'Data is required. Please complete.' answered with 'frequency unknown, following review of med records.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 09:07:59
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:41:47
	(b) (4)	
	System	23 Mar 2021 23:41:06
	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '6 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:21:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
User entered empty.	System	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
User entered empty.	System	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:14
User entered empty.	System	23 Mar 2021 23:41:06

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:23:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:23:45
Data point term sent to Coder Coding entries removed.	System Mitchell Stern (b) (4)	07 Apr 2021 17:24:08 07 Apr 2021 17:23:25
User signature succeeded.	(b) (4) Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:14:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:14:04
Data point term sent to Coder User entered 'Vancomycin'	System Mitchell Stern (b) (4)	23 Mar 2021 23:43:16 23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:09
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	07 Apr 2021 17:23:25
	(b) (4)	
User entered 'OSTEOMYELITIS OF LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT'	Mitchell Stern (b) (4)	07 Apr 2021 17:23:25
reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'osteomyelitis of left foot'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per CDM, re-query: Response noted. Please review "Dose per administration", "Dose Unit" and "Frequency" and update with either a number/unit/frequency or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 08:48:54
Query 'Per CDM, re-query: Response noted. Please review "Dose per administration", "Dose Unit" and "Frequency" and update with either a number/unit/frequency or "UNK" if unknown. Thank you. ' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	25 Mar 2021 14:53:55
User entered 'UNK' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	25 Mar 2021 14:53:25
User opened query 'Per CDM, re-query: Response noted. Please review "Dose per administration", "Dose Unit" and "Frequency" and update with either a number/unit/frequency or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:06:49
Query 'Per CDM, re-query: Response noted. Please review "Dose per administration", "Dose Unit" and "Frequency" and update with either a number/unit or "UNK" if unknown. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:06:39
User opened query 'Per CDM, re-query: Response noted. Please review "Dose per administration", "Dose Unit" and "Frequency" and update with either a number/unit or "UNK" if unknown. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:02:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 09:01:51
Query 'Data is required. Please complete.' answered with 'dose unknown, following review of med records.' (Site from System).	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:42:46
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 23:42:34

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
User entered empty.	Mitchell Stern (b) (4) (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Per Query Resolution	Mitchell Stern (b) (4)	25 Mar 2021 14:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'dose unknown, following review of med records.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 09:01:53
User opened query 'Data is required. Please complete.' (Site from System).	Mitchell Stern (b) (4)	23 Mar 2021 23:42:49
User entered empty.	(b) (4)	
	System	23 Mar 2021 23:42:34
	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:37
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'UNK' reason for change: Per Query Resolution	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 14:53:25
	(b) (4)	
	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'unknown (UNKNOWN)' reason for change: Per Query Resolution	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Mitchell Stern (b) (4)	25 Mar 2021 14:53:25
Query 'Data is required. Please complete.' answered with 'frequency unknown, following review of med records.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 09:01:55
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:43:00
	(b) (4)	
	System	23 Mar 2021 23:42:34
	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:22:58
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:23:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '0'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:23:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:23:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '6 Mar 2021'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:23:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'No (N)'	Mitchell Stern (b) (4)	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
User entered empty.	System	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
User entered empty.	System	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:01:19
User entered empty.	System	23 Mar 2021 23:42:34

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:43
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 21:44:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 21:44:12
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 21:42:46
User entered 'Aspirin'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:45
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Cardiovascular health'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '81'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:24:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:37
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 21:42:39
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:42:39

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:42:39

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 21:42:39

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:17:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:17:52
Data point term sent to Coder Coding entries removed.	System Mitchell Stern (b) (4)	07 Apr 2021 17:25:08 07 Apr 2021 17:24:31
User signature succeeded.	(b) (4) Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:15:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:15:41
Data point term sent to Coder User entered 'Cefazolin'	System Mitchell Stern (b) (4) (b) (4)	31 Mar 2021 17:45:22 31 Mar 2021 17:45:00

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:25:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:00
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	07 Apr 2021 17:24:31
	(b) (4)	
User entered 'OSTEOMYELITIS OF THE LEFT FOOT, NECROTIZING FASCIITIS OF LEFT FOOT' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	07 Apr 2021 17:24:31
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Osteomyelitis of the left foot'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '2'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'g (g)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'other (OTHER)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'every 8 hours'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '9 Mar 2021'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
	(b) (4)	
DataPoint Un-verified.	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
User entered '13 Apr 2021' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 19:58:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:00
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:45:00

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:45:00

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:45:00

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:32:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:32:05
	(b) (4)	
Data point term sent to Coder	System	31 Mar 2021 17:46:23
User entered 'Clopidogrel'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Peripheral vascular disease'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '75'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:26:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:28:17
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:28:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:28:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '10 Mar 2021'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:28:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:29:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:29:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:29:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	31 Mar 2021 17:45:44
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 17:45:44

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 17:45:44

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 17:45:44

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:21:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:31:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:10:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:10:07
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:47
User closed query 'PER CDM: Response noted, however kindly update the response from option YES or NO for the concomitant procedures performed.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:21:21
Query 'PER CDM: Response noted, however kindly update the response from option YES or NO for the concomitant procedures performed.' answered with 'updated' (Site from DM).	Susan Reed (b) (4)	28 Sep 2020 20:11:32
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	28 Sep 2020 20:11:26
User opened query 'PER CDM: Response noted, however kindly update the response from option YES or NO for the concomitant procedures performed.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:35:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 05:34:45
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	Susan Reed (b) (4)	25 Sep 2020 21:06:21
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 21:06:06
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	25 Sep 2020 21:06:06
User entered 'Yes (Y)'	Susan Reed (b) (4)	25 Sep 2020 21:05:49

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:33:42
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '21 Sep 2020'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:11
	(b) (4)	

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:33:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered 'Electrocardiogram'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:11
	(b) (4)	

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:33:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User closed query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#1 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:49:14
Query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#1 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:13:55
User opened query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#1 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 02:22:03
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:11
	(b) (4)	

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:33:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 20:53:11
	(b) (4)	

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:34:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '21 Sep 2020'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:32

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'CT of the head and cervical spine'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:32

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	15 Jan 2021 20:53:32

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 20:53:32

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:13
Query 'This was done on 02Mar2021 per source document. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:38:12
User opened query 'This was done on 02Mar2021 per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:36:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:29
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '21 Sep 2020'	Mitchell Stern (b) (4)	15 Jan 2021 20:54:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:35:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'X-ray of the chest, left shoulder, left foot'	Mitchell Stern (b) (4)	15 Jan 2021 20:54:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	15 Jan 2021 20:54:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 20:54:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:37:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '22 Sep 2020'	Mitchell Stern (b) (4)	15 Jan 2021 20:54:31

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:37:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'MRI of the left foot'	Mitchell Stern (b) (4)	15 Jan 2021 20:54:31

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:37:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User closed query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#3 or #4 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 12:49:37
Query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#3 or #4 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:15:49
User opened query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#3 or #4 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 02:22:21
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 20:54:31

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:37:59
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 20:54:31

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '22 Sep 2020'	Mitchell Stern (b) (4)	15 Jan 2021 20:55:06

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Transthoracic Echocardiogram'	Mitchell Stern (b) (4)	15 Jan 2021 20:55:06

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	15 Jan 2021 20:55:06

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 20:55:06

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '4 Mar 2021' reason for change: New Information	(b) (4)	
	Mitchell Stern (b) (4)	22 Mar 2021 22:48:13
User entered '3 Mar 2021'	(b) (4)	
	Mitchell Stern (b) (4)	12 Mar 2021 20:47:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'MRI OF LEFT FOOT and left ankle'	(b) (4)	
reason for change: New Information	Mitchell Stern (b) (4)	22 Mar 2021 22:48:03
User entered 'MRI of left foot'	(b) (4)	
	Mitchell Stern (b) (4)	12 Mar 2021 20:47:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	12 Mar 2021 20:47:34

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	12 Mar 2021 20:47:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '4 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:49:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Staged deep incision and drainage with fasciotomy through multiple layers with excisional debidment of all non-viable tissue and 3rd metatarsal resection, left foot.'	Mitchell Stern (b) (4)	22 Mar 2021 22:49:57

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:49:57

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:49:57

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '9 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Insertion of left peripherally inserted central catheter'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:51:12

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '4 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:58

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'X-Ray of left foot and left ankle'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:58

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:51:58

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:51:58

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:14

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'X-ray of chest'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:14

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:59
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:14

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:22:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:52:14

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:15:36
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:42

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:15:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'X-ray of left tibia/fibula'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:42

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:16:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:52:42

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:52:42

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:21

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Ultrasound of bilateral lower extremities'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:21

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:03:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:21

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:03:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:53:21

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '2 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:37

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Electrocardiogram'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:37

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:53:37

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:38:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:53:37

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:22
User closed query 'Per ETRTR, According to SAE Osteomyelitis of Left Foot, subject had an MRI on the left foot. Please add data to Concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:55:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
Query 'Per ETRTR, According to SAE Osteomyelitis of Left Foot, subject had an MRI on the left foot. Please add data to Concomitant procedures.' answered with 'MRI of left foot already present in con procedure log' (Site from CRA).	Mitchell Stern (b) (4)	23 Mar 2021 18:49:47
User opened query 'Per ETRTR, According to SAE Osteomyelitis of Left Foot, subject had an MRI on the left foot. Please add data to Concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 00:33:10
User entered '3 Mar 2021'	Mitchell Stern (b) (4)	22 Mar 2021 22:54:20

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Continuous cardiac monitor'	Mitchell Stern (b) (4)	22 Mar 2021 22:54:20

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	22 Mar 2021 22:54:20

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	22 Mar 2021 22:54:20

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:21:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:10
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '22 Feb 2021'	Mitchell Stern (b) (4)	23 Mar 2021 20:32:46

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:21:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:58:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Angioplasty of left lower extremity'	Mitchell Stern (b) (4)	23 Mar 2021 20:32:46

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:21:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:58:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	23 Mar 2021 20:32:46

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:21:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:58:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered empty.	Mitchell Stern (b) (4)	23 Mar 2021 20:32:46

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'US'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered '90038'	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '28/Sep/2020 08:33'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:24
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'US'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:31:30
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '28/Sep/2020 15:35'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:31:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:35:04
Signature has been broken.	(b) (4), (b) (6)	28 Sep 2020 19:35:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:01:00
User entered '07/Oct/2020 19:16'	System	07 Oct 2020 19:16:28

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:01:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:27:30
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 19:16:28

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:05:43
User entered '13/Oct/2020 15:27'	System	13 Oct 2020 15:27:40

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Oct 2020 19:37:10
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 15:27:40

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered '90038'	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'US'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:05:52
User entered '18/Oct/2020 15:38'	System	18 Oct 2020 19:38:51

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 22:09:07
User entered 'I'	(b) (4), (b) (6)	18 Oct 2020 19:38:51

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered '90038'	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:06:13
User entered '21/Oct/2020 22:09'	System	21 Oct 2020 22:09:33

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:06:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:34:37
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 22:09:33

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	(b) (4) Jesse Clark (b) (4) (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:06:20
User entered '28/Oct/2020 09:34'	System	28 Oct 2020 13:34:45

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:59:49
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:07:24
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 13:34:45

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 01:08:28
User entered '17/Nov/2020 21:00'	System	17 Nov 2020 21:00:02

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 17:48:36
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 01:08:31
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 21:00:02

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '04/Jan/2021 17:48'	(b) (4) System	04 Jan 2021 17:48:55

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:02:02
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 17:48:55

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '12/Feb/2021 12:02'	(b) (4) System	12 Feb 2021 17:02:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:02:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
User entered 'US'	(b) (4) System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered '09/Mar/2021 10:55'	(b) (4) System	09 Mar 2021 15:56:00

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:56:00

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:21
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'USA-US081-2020-MRNA-1273-P301000001'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:23
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:24
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:28
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:27
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Yes (Y)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:30
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:32
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:34
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'No (N)'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:40
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Jesse'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:46
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'Clark'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '910 Vine Street'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'Los Angeles'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:57
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:33:07
User entered 'CA'	System	28 Sep 2020 12:32:49

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:30:59
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:16:16
Un-reviewed for Safety.	System	28 Sep 2020 19:35:04
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered empty.	System	28 Sep 2020 19:35:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '90038'	Jesse Clark (b) (4)	28 Sep 2020 19:05:06
	(b) (4)	

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:31:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 19:34:47
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered 'US'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	05 Apr 2021 13:57:01
User entered '11'	System	09 Mar 2021 15:56:00
User entered '10'	System	12 Feb 2021 17:02:49
User entered '9'	System	04 Jan 2021 17:48:55
User entered '8'	System	17 Nov 2020 21:00:02
User entered '7'	System	28 Oct 2020 13:34:45
User entered '6'	System	21 Oct 2020 22:09:33
User entered '5'	System	18 Oct 2020 19:38:51
User entered '4'	System	13 Oct 2020 15:27:40
User entered '3'	System	07 Oct 2020 19:16:28
Signature has been broken.	System	28 Sep 2020 19:35:04
User entered '2'	System	28 Sep 2020 19:35:04
User signature succeeded.	Jesse Clark (b) (4)	28 Sep 2020 19:05:18
	(b) (4)	
User entered '1'	System	28 Sep 2020 12:33:23

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
User entered '05/Apr/2021 09:56'	(b) (4) System	05 Apr 2021 13:57:01

US3682134

Folder: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:01

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '15/Mar/2021 07:22'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '22/Mar/2021 13:58'	System	22 Mar 2021 17:58:36

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 17:58:36

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '23/Mar/2021 12:00'	System	23 Mar 2021 16:00:34

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:00:40
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 16:00:34

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '24/Mar/2021 15:33'	System	24 Mar 2021 19:33:06

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 19:33:13
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 19:33:06

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
User entered '25/Mar/2021 09:01'	System	25 Mar 2021 13:01:33

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:01:33

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
	(b) (4)	
User entered '05/Apr/2021 09:17'	System	05 Apr 2021 13:18:00

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:27
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 13:18:00

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'USA-US081-2021-MRNA-1273-P301000012'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Yes (Y)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'No (N)'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Jesse'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'Clark'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:22:04
User entered 'CA'	System	15 Mar 2021 14:20:20

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:49:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:52:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:58:43
User entered 'US'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Apr 2021 15:58:45
User entered '6'	System	05 Apr 2021 13:18:00
User entered '5'	System	25 Mar 2021 13:01:33
User entered '4'	System	24 Mar 2021 19:33:06
User entered '3'	System	23 Mar 2021 16:00:34
User entered '2'	System	22 Mar 2021 17:58:36
User entered '1'	System	15 Mar 2021 14:22:25

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:21:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User entered '22/Apr/2021 10:58'	(b) (4) System	22 Apr 2021 15:58:45

US3682134

Folder: SAE USA-US081-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:21:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:58:45