

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

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:10:39

All time stamps listed in this document are displayed in GMT

US3682134

Form: Participant Creation

Generated On: 26 Nov 2020 11:10:39

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:10:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:10:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

Condition	DIABETES MELLITUS, TYPE II
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

Condition	GENERALIZED CHRONIC PAIN
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

Condition	LEFT FOOT OPEN ULCER
Start date (dd MMM yyyy)	UN MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

Condition	RIGHT BELOW KNEE AMPUTATION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

Condition	OBESITY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

Condition	MRSA INFECTION OF RIGHT LOWER EXTREMITY LEADING TO BELOW KNEE AMPUTATION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

Generated On: 26 Nov 2020 11:10:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 11:10:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:10:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 ☒

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 ☒

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

		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: 26 Nov 2020 11:10:39

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 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

		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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:10:39

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	15 OCT 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:10:39

Collection date (<i>dd MMM yyyy</i>)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 ☒

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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 ☒

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

Yes ☐	
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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

Yes ☐	
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

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:10:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please 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: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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26 DEC 2020 00:01

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30 DEC 2020 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

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06 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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09 JAN 2021 00:01

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13 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

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20 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

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27 JAN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

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10 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

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17 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

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24 FEB 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

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03 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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20 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: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 194

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[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: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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26 MAR 2022 00:01

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30 MAR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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09 APR 2022 00:01

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13 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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16 APR 2022 00:01

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20 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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23 APR 2022 00:01

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27 APR 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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30 APR 2022 00:01

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04 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

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11 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

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18 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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21 MAY 2022 00:01

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25 MAY 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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28 MAY 2022 00:01

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01 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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04 JUN 2022 00:01

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08 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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11 JUN 2022 00:01

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15 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 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: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

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10 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

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17 SEP 2022 00:01

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21 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3682134

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:10:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3682134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:10:39

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)

Generated On: 26 Nov 2020 11:10:39

AEID	USA-US081-2020-MRNA-1273-P30 1000001
Adverse event	SYNCOPE, WORSENER FROM BASELINE
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)	24 SEP 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	True
Hospital Admission Date (dd MMM yyyy)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	24 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

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.

Serious Adverse Event Derived (CSA Programming Field Only)

1

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

AEID	
Adverse event	CONCUSSION
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)	24 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)	4 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	338 of 2064

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

AEID	
Adverse event	CELLULITIS 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	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
Admitted to ICU Derived (CSA Programming Field Only)	0

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:10:39

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

Yes ☒

No ☐

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

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intraocular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

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 ☐ Intraocular ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:39

Name of Medication	BACTRIM
Prophylaxis	Yes ☐ No ☒
Indication	CELLULITIS/OSTEOMYELITIS OF LEFT FOOT
Dose per administration	1 DS
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 ☐

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 06 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:10:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3682134

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:10:39

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

US3682134

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:10:39

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

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8

US3682134

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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)

Generated On: 26 Nov 2020 11:10:39

SAEID	USA-US081-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	8
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

Audit

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

US3682134

Form: Participant Creation

Generated On: 26 Nov 2020 11:10:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3682134'	RWS_ENDPOINT ENDPOINT (b) (4) 	17 Sep 2020 20:54:08

US3682134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4)	17 Sep 2020 21:25:14
	(b) (4)	

US3682134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	17 Sep 2020 20:54:10

US3682134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sandy MacNicoll (b) (4)	17 Sep 2020 21:25:14
	(b) (4)	

US3682134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	17 Sep 2020 21:25:14

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Sep 2020 20:54:11

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Age](#)

Audit	User	Time (GMT)
User entered '46'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '46'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

White

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please clarify subject's Race, as HISPANIC is an ethnicity.' (Site from DM).	(b) (4), (b) (6)	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

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

Unknown

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:27:56

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

[Protocol Version](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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).	System	17 Sep 2020 21:28:08
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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).	System	17 Sep 2020 21:28:08
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:08

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Sep 2020 20:54:10

US3682134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:10:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:32

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: 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
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2011'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2011'	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:18

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2008'	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:37

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2015'	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:37:53

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

[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) (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) (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. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	29 Oct 2020 03:55:44
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. ' answered with 'Updated to reflect pain is generalized.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	28 Oct 2020 17:52:40
Coding entries removed.	Jesse Clark (b) (4) (b) (4)	28 Oct 2020 17:52:31
User entered 'Generalized CHRONIC PAIN' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	28 Oct 2020 17:52:31
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. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	28 Oct 2020 08:14:49
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) (b) (4)	17 Sep 2020 21:39:41

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Sep 2020 21:39:41
User: Coder System - version MedDRA\\23.0.	(b) (4)	
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)	

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	23 Nov 2020 20:33:03
User entered 'un UNK 2010'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:38:05

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un Mar 2019'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Mar 2019'	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:38:37

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	17 Sep 2020 21:39:00

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Sep 2020 21:39:00

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

Condition

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2018'	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:08:12

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Susan Reed (b) (4) (b) (4)	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:18:39

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2010' reason for change: Data Entry Error	(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: 26 Nov 2020 11:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '2010'	System	15 Oct 2020 20:47:29

US3682134

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '14:00'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:00'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '67' in	Jesse Clark (b) (4)	17 Sep 2020 21:44:28
DataPoint set to visible.	(b) (4) System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '283' lb	Jesse Clark (b) (4)	17 Sep 2020 21:44:28
DataPoint set to visible.	(b) (4) System	17 Sep 2020 21:28:26

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 21:44:28

US3682134

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:39

US3682134

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:28:39

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '1'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:29:09

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4)	17 Sep 2020 21:26:07
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Sandy MacNicoll (b) (4)	17 Sep 2020 21:26:07
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Sep 2020 21:26:07

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '146245'	RWS_ENDPOINT ENDPOINT (b) (4) 	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Sep 2020 21:14:25

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:10:13
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:39

[Liver Disease](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '14:00'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	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: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '118'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	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: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	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: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 11:10:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '15:22'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '103'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:43:33
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 22:43:33

US3682134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:06:40
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:06:40
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '14:51'	Sandy MacNicoll (b) (4)	17 Sep 2020 22:03:50
	(b) (4)	

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:51'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 22:03:50

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:30'	(b) (4), (b) (6)	17 Sep 2020 21:58:06

US3682134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:35'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:58:42

US3682134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sandy MacNicoll (b) (4) (b) (4)	17 Sep 2020 22:44:27

US3682134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:44:27

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:36:39
User entered 'Yes (Y)'	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:36:39
User entered '98.9'	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:36:39
User entered '17 Sep 2020 18:36'	System	18 Sep 2020 01:36:39

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:00:46
User entered 'Yes (Y)'	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:00:46
User entered '99.1'	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:00:46
User entered 'No (N)'	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:00:46
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 19:00:46

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:12
User entered 'Yes (Y)'	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:12
User entered '98.7'	System	19 Sep 2020 21:44:12

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:00:58
User entered 'Yes (Y)'	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:00:58
User entered '99.0'	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:00:58
User entered '20 Sep 2020 12:00'	System	20 Sep 2020 19:00:58

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:00:35
User entered 'Yes (Y)'	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:00:35
User entered '98.8'	System	21 Sep 2020 19:00:35

US3682134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:20
User entered 'No (N)'	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:20
User entered 'No (N)'	System	18 Sep 2020 01:37:20

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:23', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eb0d398a-da03-4f2d-8621-dd83f12940fa'	System	18 Sep 2020 19:01:32
User entered 'None (1)'	System	18 Sep 2020 19:01:32

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cacf9'	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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:43:45
User entered 'No (N)'	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:43:45
User entered 'No (N)'	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:43:40', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'eabc9afc-1702-4c73-9512-c487b84cacf9'	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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:43:45
User entered '19 Sep 2020 14:43'	System	19 Sep 2020 21:43:45

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:13
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:13

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcb79b-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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:00:42
User entered 'No (N)'	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: '9bcb79b-b63d-4b5c-8f4d-dad4870375db'	System	21 Sep 2020 19:00:42
User entered 'No (N)'	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:00:39', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '9bcb79b-b63d-4b5c-8f4d-dad4870375db'	System	21 Sep 2020 19:00:42
User entered 'None (1)'	System	21 Sep 2020 19:00:42

US3682134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: '9bcb79b-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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 22:26:08
User entered 'None (0)'	System	17 Sep 2020 22:26:08

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:37:41
User entered 'None (0)'	System	18 Sep 2020 01:37:41

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered 'None (0)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-18T12:01:47', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'bdef95f4-e806-4e26-8251-e9ed15581831'	System	18 Sep 2020 19:01:53
User entered 'No (N)'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 19:01:53
User entered '18 Sep 2020 12:01'	System	18 Sep 2020 19:01:53

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:30
User entered 'None (0)'	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:30
User entered 'None (0)'	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:30
User entered 'None (0)'	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-19T14:44:26', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '011ad64f-aba2-419c-9781-a634b8530dee'	System	19 Sep 2020 21:44:30
User entered 'No (N)'	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 21:44:30
User entered '19 Sep 2020 14:44'	System	19 Sep 2020 21:44:30

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered 'None (0)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-20T12:01:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'cf2500e9-4191-4347-a3d7-fa32f386ef7c'	System	20 Sep 2020 19:01:26
User entered 'No (N)'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 19:01:26
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:26

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered 'None (0)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered 'None (0)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered 'None (0)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered 'None (0)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered 'None (0)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-09-21T12:01:02', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '7a46383d-0315-4b53-934c-99960904541e'	System	21 Sep 2020 19:01:25
User entered 'No (N)'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 19:01:25
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 19:01:25

US3682134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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)	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)	25 Sep 2020 20:44:23

US3682134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	25 Sep 2020 20:44:29

US3682134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:44:29

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:10

US3682134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:16:15

US3682134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:16:15

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Christopher Blades (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:04:40

US3682134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:02

US3682134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 22:05:02

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Christopher Blades (b) (4)	15 Oct 2020 22:05:13
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Oct 2020 22:05:13

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '13:12'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	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: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:10:39

Pulse (xxx)

Audit	User	Time (GMT)
User entered '112'	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: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '133'	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: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	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: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4)	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '15:10'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Christopher Blades (b) (4)	15 Oct 2020 22:20:43
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:10:39

Pulse (xxx)

Audit	User	Time (GMT)
User entered '108'	Christopher Blades (b) (4)	15 Oct 2020 22:20:43
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '143'	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: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	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: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 22:20:43

US3682134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:25

US3682134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:25

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	Christopher Blades (b) (4)	15 Oct 2020 22:05:45
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '14:39'	Christopher Blades (b) (4) (b) (4)	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christopher Blades (b) (4)	15 Oct 2020 22:05:45
	(b) (4)	

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 22:05:45

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:32'	(b) (4), (b) (6)	16 Oct 2020 01:26:54

US3682134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(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: 26 Nov 2020 11:10:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:15'	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 01:27:08

US3682134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:07

US3682134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 20:33:07

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:11:44
User entered 'Yes (Y)'	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:11:44
User entered '15 Oct 2020 15:11'	System	15 Oct 2020 22:11:44

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:29:48
User entered '98.7'	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:29:48
User entered '15 Oct 2020 19:29'	System	16 Oct 2020 02:29:48

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:00:37
User entered 'Yes (Y)'	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:00:37
User entered '16 Oct 2020 12:00'	System	16 Oct 2020 19:00:37

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:00:58
User entered 'Yes (Y)'	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:00:58
User entered '98.7'	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:00:58
User entered '17 Oct 2020 12:00'	System	17 Oct 2020 19:00:58

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:28
User entered '99.1'	System	18 Oct 2020 19:00:28

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:30
User entered 'Yes (Y)'	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:30
User entered '98.8'	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:30
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 19:00:30

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:01:55
User entered 'Yes (Y)'	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:01:55
User entered '98.8'	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:01:55
User entered '21 Oct 2020 02:01'	System	21 Oct 2020 09:01:55

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:00:27
User entered 'Yes (Y)'	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:00:27
User entered '99.0'	System	21 Oct 2020 19:00:27

US3682134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:03', 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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '15 Oct 2020 15:12'	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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:03
User entered 'No (N)'	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:03
User entered 'No (N)'	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:03
User entered '15 Oct 2020 19:29'	System	16 Oct 2020 02:30:03

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:37', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd'	System	16 Oct 2020 19:00:59
User entered 'None (1)'	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:00:54', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '83b425ce-c9f9-48f6-9cbd-2945ae0da6bd'	System	16 Oct 2020 19:00:59
User entered 'None (1)'	System	16 Oct 2020 19:00:59

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:12
User entered 'No (N)'	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:12
User entered 'No (N)'	System	17 Oct 2020 19:01:12

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:05', 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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:30', 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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:39
User entered 'No (N)'	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:39
User entered 'No (N)'	System	18 Oct 2020 19:00:39

US3682134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:12:37
User entered 'None (0)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:12:37
User entered 'None (0)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:12:37
User entered 'None (0)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:12:37
User entered 'None (0)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	15 Oct 2020 22:12:37
User entered 'None (0)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T15:12:32', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '34795ede-418f-4cd8-9c81-9795a00aea34'	System	15 Oct 2020 22:12:37
User entered 'No (N)'	System	15 Oct 2020 22:12:37

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered 'None (0)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-15T19:30:13', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '21682fea-2b65-4f06-8996-4ec539698515'	System	16 Oct 2020 02:30:20
User entered 'No (N)'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 02:30:20
User entered '15 Oct 2020 19:30'	System	16 Oct 2020 02:30:20

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	16 Oct 2020 19:01:17
User entered 'None (0)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-16T12:01:12', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ede882f1-c228-4dff-8c41-f3dbac97811f'	System	16 Oct 2020 19:01:17
User entered 'No (N)'	System	16 Oct 2020 19:01:17

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered 'None (0)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-17T12:01:22', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8cf18373-581f-490e-9a03-87dbed5dbf79'	System	17 Oct 2020 19:01:30
User entered 'No (N)'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Oct 2020 19:01:30
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 19:01:30

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered 'None (0)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-18T12:00:51', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'aed0292c-13d2-4826-a746-d3a52cbbec66'	System	18 Oct 2020 19:00:57
User entered 'No (N)'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Oct 2020 19:00:57
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered 'None (0)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-19T12:00:53', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: '8abd8323-cc6d-450d-b2f9-55ed743507b6'	System	19 Oct 2020 19:00:57
User entered 'No (N)'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 19:00:57
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 19:00:57

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:02:22
User entered 'None (0)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:02:22
User entered 'None (0)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:02:22
User entered 'None (0)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:02:22
User entered 'None (0)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	21 Oct 2020 09:02:22
User entered 'None (0)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T02:02:18', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'c9d9b9bc-4f46-4a02-b503-96806571d70e'	System	21 Oct 2020 09:02:22
User entered 'No (N)'	System	21 Oct 2020 09:02:22

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

CHILLS

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered 'None (0)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CBFBDD66-5198-4450-9BCA-D9E6EF96A434)', Time: '2020-10-21T12:00:48', User OID: 'PatientReportedOutcome (US3682134)', ODM File OID: 'ea6bfa12-c724-4293-94ad-7fa46ab4dc8b'	System	21 Oct 2020 19:01:05
User entered 'No (N)'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Oct 2020 19:01:05
User entered '21 Oct 2020 12:00'	System	21 Oct 2020 19:01:05

US3682134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:28

US3682134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	22 Oct 2020 20:33:31

US3682134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 20:33:31

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:18

US3682134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	29 Oct 2020 20:44:22

US3682134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 20:44:22

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:13

US3682134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:42:19

US3682134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 21:42:19

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4)	13 Nov 2020 21:36:29
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Nov 2020 21:36:29

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '13:32'	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '102'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '16'	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Christopher Blades (b) (4)	13 Nov 2020 21:37:02
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 21:37:02

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	13 Nov 2020 21:37:10

US3682134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Christopher Blades (b) (4)	13 Nov 2020 21:37:10
	(b) (4)	

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:23'	(b) (4), (b) (6)	13 Nov 2020 21:37:14

US3682134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 13:23'	System	13 Nov 2020 21:37:14

US3682134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

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: '2020-11-17T09:17:31', 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: 26 Nov 2020 11:10:39

Have you been exposed to someone with 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: '2020-11-17T09:17:36', 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: 26 Nov 2020 11:10:39

[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: '2020-11-17T09:17:40', 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: 26 Nov 2020 11:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:24:55
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:24:55

US3682134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:39

[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 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: 26 Nov 2020 11:10:39

[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 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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

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' User entered 'No (N)'	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: 26 Nov 2020 11:10:39

Have you been exposed to someone with 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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:10:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:55
User entered 'Yes (Y)'	Susan Reed (b) (4)	25 Sep 2020 20:44:43
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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, HLG: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:57:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:57:50
	(b) (4)	
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)	16 Oct 2020 20:20:31
	(b) (4)	
Coding entries removed.	Jesse Clark (b) (4)	16 Oct 2020 20:20:20
	(b) (4)	
User entered 'SYNCOPE, Worsened from baseline' reason for change: Per Query Resolution	Jesse Clark (b) (4)	16 Oct 2020 20:20:20
	(b) (4)	
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Adverse event](#)

Audit	User	Time (GMT)
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.	Coder Import (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: 26 Nov 2020 11:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:29:59
User entered 'No (N)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:32:25
User entered 'No (N)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:32:28
User entered '21 Sep 2020'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:32:32
User entered empty.	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:35:15
User entered 'No (N)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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
Query 'This end date does not match with source document. Please verify and update accordingly.' answered with 'form updated' (Site from CRA).	Susan Reed (b) (4)	16 Nov 2020 23:35:48
	(b) (4)	
User entered '24 Sep 2020' reason for change: Per Query Resolution	Susan Reed (b) (4)	16 Nov 2020 23:35:23
	(b) (4)	
User opened query 'This end date does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 19:36:22
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)	20 Oct 2020 11:10:12
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).	Jesse Clark (b) (4)	16 Oct 2020 20:20:42
	(b) (4)	
User entered '21 Sep 2020' reason for change: Per Query Resolution	Jesse Clark (b) (4)	16 Oct 2020 20:20:20
	(b) (4)	
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), (b) (6)	15 Oct 2020 12:29:24
User entered '24 Sep 2020'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:29
User entered empty.	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:31
User entered 'Grade 4 (Grade 4)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:33
User entered 'Yes (Y)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:35
User entered '0'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:42
User entered '0'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:38
User entered '1'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:41
User entered '21 Sep 2020'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:46
User entered '24 Sep 2020'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:48
User entered 'No (N)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:51
User entered empty.	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:53
User entered '0'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:54
User entered '0'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:56
User entered '0'	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: 26 Nov 2020 11:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:36:58
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4)	28 Sep 2020 18:49:32
reason for change: Data Entry Error	(b) (4)	
User entered 'Related (RELATED)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:37:03
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:37:05
User entered 'None (NONE)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
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)	16 Oct 2020 20:21:10
	(b) (4)	
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)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
User entered '0' reason for change: Per Query Resolution	(b) (4)	16 Oct 2020 20:20:20
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:10
User entered '0'	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: 26 Nov 2020 11:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:16
User entered empty.	Susan Reed (b) (4)	25 Sep 2020 21:05:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	27 Oct 2020 19:33:13
	(b) (4)	
DataPoint Un-verified.	Susan Reed (b) (4)	27 Oct 2020 19:21:25
	(b) (4)	
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	Susan Reed (b) (4)	27 Oct 2020 19:21:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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
v6.020 DTW (1102)		1501 of 2064

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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
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

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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 10.6 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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[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

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Folder: Adverse Events

Form: Adverse Events (1)

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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.' 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

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Folder: Adverse Events

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[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 21:05:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	01 Oct 2020 20:41:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:41:50
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:40:46
User entered 'Concussion'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:28
User entered 'Yes (Y)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:27:23
User entered 'No (N)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:27:26
User entered 'No (N)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:33
User entered '24 Sep 2020'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:35
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:40:08

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:37
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4)	08 Oct 2020 20:11:41
User entered 'Yes (Y)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'There is no end date in source document. Please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:45
	(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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:48
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:40:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:36:59
User entered 'No (N)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:02
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:05
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:07
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:10
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:13
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:28
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:30
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:32
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:34
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:38
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:39
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:41
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:37:43
User entered 'None (NONE)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:32
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:34
User entered '1'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:36
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
	(b) (4)	
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
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:39
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	01 Oct 2020 20:40:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:40:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:44:15
User entered 'Yes (Y)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:44:19
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:44:29
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:44:33
User entered '21 Sep 2020'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:48:54
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:02
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:13
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:34
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:36
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:50:52
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:50:55
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:50:57
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:50:59
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:03
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:05
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:07
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:09
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:11
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:13
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:15
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:17
User entered 'None (NONE)'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:21
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:24
User entered '1'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:28
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Outcome](#)

Audit	User	Time (GMT)
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
	(b) (4)	
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
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:53:15
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:37:08
	(b) (4)	

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 22:37:08

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:29
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	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: 26 Nov 2020 11:10:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:30:02
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:53:32

US3682134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 18:53:32

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:10:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:45:50
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)	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)	17 Sep 2020 21:29:18

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	18 Sep 2020 06:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 06:09:49
Data point term sent to Coder	System	17 Sep 2020 21:30:37
User entered 'Humalog insulin'	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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:06
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:45
User entered 'Diabetes Mellitus Type II'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:48
User entered '14'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:50
User entered 'Other (OTHER)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:53
User entered 'Units'	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:56
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:58
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:11
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:15
User entered 'un UNK 2008'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:17
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:22
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:25
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:03:28
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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
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

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:09
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:12
User entered 'Diabetes Mellitus Type II'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:50
User entered '1.8.'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:52
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:55
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:57
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:58
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
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) (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)	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)	17 Sep 2020 21:30:54

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:13
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:19
User entered 'un UNK 2008'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:21
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:29
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:33
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:37
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:55
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:57
User entered 'Diabetes Mellitus Type II'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:00
User entered '10'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:02
User entered 'Other (OTHER)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:06
User entered 'Units'	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:13
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:15
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	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: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:20
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:45
User entered 'un UNK 2008'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:47
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:51
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:54
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:15:56
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:07
User entered 'No (N)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:17
User entered 'Hypertension'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:23
User entered '3.125'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:26
User entered 'mg (mg)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:28
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:31
User entered 'once daily (QD)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:33
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:40
User entered 'Oral (ORAL)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:48
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:51
User entered 'un UNK 2011'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:53
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:55
User entered 'Yes (Y)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:58
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:01
User entered 'No (N)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:03
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	System	17 Sep 2020 21:32:39
User entered 'Diltiazem'	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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:23
User entered 'No (N)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:27
User entered 'Hypertension'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:32
User entered '30'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:34
User entered 'mg (mg)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:36
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:40
User entered 'twice daily (BID)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:42
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:44
User entered 'Oral (ORAL)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:51
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:55
User entered 'un UNK 2011'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:57
User entered '0'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:59
User entered 'Yes (Y)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:01
User entered empty.	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:30
User entered 'No (N)'	Jesse Clark (b) (4)	17 Sep 2020 21:32:37
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:40
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:46
User entered 'Diabetes Mellitus Type II'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:50
User entered '1000'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:52
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:54
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:00
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:01
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:04
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:06
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:11
User entered 'un UNK 2008'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:15
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:17
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:20
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	24 Nov 2020 04:16:04
Data point term sent to Coder Coding entries removed.	System Susan Reed (b) (4)	23 Nov 2020 21:42:47 23 Nov 2020 21:42:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4)	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) (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) (b) (4)	17 Sep 2020 21:34:44
Data point term sent to Coder User entered 'Tizanidine'	System Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:33:43 17 Sep 2020 21:33:38

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:47
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
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 16:36:32
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 'form updated' (Site from DM).	Susan Reed (b) (4)	23 Nov 2020 21:42:50
DataPoint Un-verified.	Susan Reed (b) (4)	23 Nov 2020 21:42:42
User entered 'CHRONIC PAIN - generalized' reason for change: Data Entry Error	Susan Reed (b) (4)	23 Nov 2020 21:42:42
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 14:52:41
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

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:29
User entered '4'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:34
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:37
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:43
User entered 'three times daily (TID)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:45
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:32
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:34
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:38
User entered 'un UNK 2010'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:39
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:41
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:43
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:46
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	17 Sep 2020 21:35:47
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 21:35:47
Data point term sent to Coder	System	17 Sep 2020 21:34:44
User entered 'Pravastatin'	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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:59
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:10
User entered 'Hyperlipidemia'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:13
User entered '20'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:15
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:17
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:22
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:25
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:42
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:44
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:53
User entered 'un UNK 2015'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:55
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:57
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:00
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:02
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	24 Nov 2020 03:39:04
Data point term sent to Coder Coding entries removed.	System Susan Reed (b) (4)	23 Nov 2020 20:29:18 23 Nov 2020 20:28:57
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	17 Sep 2020 21:36:48
Data point term sent to Coder User entered 'Amitriptyline'	System Jesse Clark (b) (4) (b) (4)	17 Sep 2020 21:35:45 17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:19
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
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
DataPoint Un-verified.	Susan Reed (b) (4)	23 Nov 2020 20:28:57
User entered 'CHRONIC PAIN - Generalized' reason for change: Data Entry Error	Susan Reed (b) (4)	23 Nov 2020 20:28:57
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

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:30
User entered '10'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:32
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:34
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:39
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:42
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:51
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:53
User entered empty.	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: 26 Nov 2020 11:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	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)	17 Sep 2020 21:35:13

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:59
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:01
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:02
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:04
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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 'Tradjenta'	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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:12
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:22
User entered 'Diabetes Mellitus Type II'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
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). DataPoint Un-verified.	Susan Reed (b) (4) (b) (4)	23 Nov 2020 22:00:09
	Susan Reed (b) (4) (b) (4)	23 Nov 2020 21:49:41
User entered '5' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	23 Nov 2020 21:49:41
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). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 14:57:24
	(b) (4), (b) (6)	27 Oct 2020 20:24:27
User entered '50'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:28
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:03
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:17
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:19
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:23
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:25
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:37
User entered 'un UNK 2008'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:39
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:41
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:43
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:31:44
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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) (b) (4)	24 Nov 2020 16:24:13
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:30
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
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 16:37:55
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 'Query resolved. See medical history entry, "generalized chronic pain."' (Site from DM). DataPoint Un-verified.	Mitchell Stern (b) (4)	24 Nov 2020 16:24:57
	(b) (4)	
	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. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:57:54
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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:56
User entered '50'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:58
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:07
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:42
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:44
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:51
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:48
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:53
User entered 'un UNK 2010'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:54
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:35:57
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:00
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:02
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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) (b) (4)	24 Nov 2020 17:16:59
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:11
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication of Mitchell Stern this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate.	(b) (4)	24 Nov 2020 17:17:08
' answered with 'query resolved' (Site from DM). DataPoint Un-verified.	(b) (4)	
	Mitchell Stern (b) (4)	24 Nov 2020 17:16:59
User entered 'Heartburn prevention' reason for change: Data Entry Error	(b) (4)	
	Mitchell Stern (b) (4)	24 Nov 2020 17:16:59
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.	(b) (4), (b) (6)	23 Nov 2020 14:58:45
' (Site from DM). 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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:20
User entered '20'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:22
User entered 'mg (mg)'	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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:23
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:30
User entered 'once daily (QD)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:32
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:35
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:36
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:41
User entered 'un UNK 2015'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:43
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:45
User entered 'Yes (Y)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:48
User entered empty.	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:50
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:18
User entered 'No (N)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:37
User entered 'Headaches as a result of a concussion'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:41
User entered '1600'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:43
User entered 'mg (mg)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:45
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:47
User entered 'as needed (PRN)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:49
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:54
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:51
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:38:11
User entered '24 Sep 2020'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:38:13
User entered '0'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
	(b) (4)	
User entered 'Yes (Y)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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
	(b) (4)	
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
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:39:27
User entered 'No (N)'	Susan Reed (b) (4)	01 Oct 2020 20:43:59
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Oct 2020 05:52:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 05:52:28
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 22:38:43
User entered 'Vancomycin'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:39:42
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:40
User entered 'Cellulitis/Osteomyelitis of Left Foot'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:50
User entered '2'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:55
User entered 'g (g)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:45
User entered 'once (ONCE)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:49
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:51
User entered 'Intravenous (INTRAVENOUS)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:57
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:58
User entered '21 Sep 2020'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:44:00
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:44:01
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:44:04
User entered '21 Sep 2020'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:44:58
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:38:01
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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 22:40:47
User entered 'Zosyn'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:40
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:46
User entered 'Cellulitis/Osteomyelitis of Left Foot'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:53
User entered 'Per Pharmacy'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:58
User entered 'Other (OTHER)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:29
User entered 'Dosing "Per Pharmacy"'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:35
User entered 'other (OTHER)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:37
User entered "'Per Pharmacy'"	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:39
User entered 'Intravenous (INTRAVENOUS)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:42
User entered empty.	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:51
User entered '21 Sep 2020'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:11
User entered '0'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:14
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:20
User entered '24 Sep 2020'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:26
User entered 'No (N)'	Jesse Clark (b) (4)	12 Oct 2020 22:39:57
	(b) (4)	

US3682134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:49:41
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
User entered 'Bactrim'	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: 26 Nov 2020 11:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:49:51
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:49:55
User entered 'Cellulitis/Osteomyelitis of Left Foot'	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: 26 Nov 2020 11:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:49:58
User entered '1 DS'	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: 26 Nov 2020 11:10:39

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:58
User entered empty.	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: 26 Nov 2020 11:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:00
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:02
User entered empty.	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: 26 Nov 2020 11:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:05
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:10:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:08
User entered empty.	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: 26 Nov 2020 11:10:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:13
User entered '24 Sep 2020'	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: 26 Nov 2020 11:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:15
User entered '0'	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: 26 Nov 2020 11:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:17
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:21
User entered '06 Oct 2020'	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: 26 Nov 2020 11:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:23
User entered 'No (N)'	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: 26 Nov 2020 11:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 22:40:46

US3682134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:10:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: SAE USA-US081-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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 '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
	(b) (4)	
User entered empty.	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 (2)

Generated On: 26 Nov 2020 11:10:39

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 00:31:32
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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	13 Nov 2020 19:01:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:27:30
User entered '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	13 Nov 2020 19:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Oct 2020 19:37:10
User entered '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	13 Nov 2020 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 22:09:07
User entered '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	13 Nov 2020 19:06:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:34:37
User entered '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	17 Nov 2020 20:59:49
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:07:24
User entered '1'	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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: 26 Nov 2020 11:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

[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: 26 Nov 2020 11:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:10:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:10:39

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)	18 Nov 2020 01:08:31
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 21:00:02