

US3572134 (Prod: Laguna Clinical Research Associates)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:11

All time stamps listed in this document are displayed in GMT

US3572134

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:11

[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 09:37:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 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 09:37:11

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	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 09:37:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

Condition	HYPOGLYCEMIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:20
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	241.4 lb
BMI (<i>xxx.x</i>)	31.91548 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 09:37:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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)	False

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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)	True
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 09:37:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 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 09:37:11

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

What was the participant's randomization number? 109673

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

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 09:37:11

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

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 09:37:11

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	28 AUG 2020
What was the treatment time? (00:00-23:59)	13:15 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 13:15
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 AUG 2020

Collection time (*00:00-23:59*)

12:23 (24 HR)

Collection date and time (derived)

28 AUG 2020 12:23

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:11

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 28 AUG 2020 14:01

PC Open Date & Time 28 AUG 2020 13:35

PC Close Date & Time 28 AUG 2020 16:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 28 AUG 2020 20:43

PC Open Date & Time 28 AUG 2020 17:00

PC Close Date & Time 29 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 22:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 14:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 13:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:24

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:02

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 14:02

PC Open Date & Time

28 AUG 2020 13:35

PC Close Date & Time

28 AUG 2020 16:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:43

PC Open Date & Time

28 AUG 2020 17:00

PC Close Date & Time

29 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 22:44

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 14:50

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:24

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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

No ☒

Yes ☐

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

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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

No ☒

Yes ☐

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

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	29 AUG 2020 22:44
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	30 AUG 2020 14:52
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	31 AUG 2020 12:23
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	01 SEP 2020 13:20
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	02 SEP 2020 19:26
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	03 SEP 2020 14:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

04 SEP 2020 12:28

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 05 SEP 2020 12:46

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

07 SEP 2020 17:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 12

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 08 SEP 2020 16:32

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 SEP 2020 12:29
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 SEP 2020 12:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	07 SEP 2020 17:48
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 SEP 2020 16:32
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3572134

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:27
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3572134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	29 SEP 2020
What was the treatment time? (00:00-23:59)	11:02 (24 HR)
Treatment Date and Time (derived)	29 SEP 2020 11:02
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:46 (24 HR)
Collection date and time (derived)	29 SEP 2020 10:46

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 11:35

PC Open Date & Time

29 SEP 2020 11:22

PC Close Date & Time

29 SEP 2020 13:52

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 04:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 23:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 03 OCT 2020 17:39

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 17:24

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 11:36

PC Open Date & Time

29 SEP 2020 11:22

PC Close Date & Time

29 SEP 2020 13:52

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 23:09

PC Open Date & Time

29 SEP 2020 14:47

PC Close Date & Time

30 SEP 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 04:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 23:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:50

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 17:39

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 17:25

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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

No ☒

Yes ☐

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

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☒
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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

No ☒

Yes ☐

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

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	01 OCT 2020 04:15
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	01 OCT 2020 23:29
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	02 OCT 2020 12:51
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	03 OCT 2020 17:41
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 ☒

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

Yes ☐	
PC Time stamp	04 OCT 2020 17:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

		Yes ☐
PC Time stamp		
PC Open Date & Time		05 OCT 2020 12:00
PC Close Date & Time		06 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 06 OCT 2020 12:47

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 06 OCT 2020 12:47

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	06 OCT 2020 12:46

PC Open Date & Time	06 OCT 2020 12:00

PC Close Date & Time	07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 OCT 2020 12:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 06 OCT 2020 12:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 07 OCT 2020 15:28

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

08 OCT 2020 16:18

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

10 OCT 2020 06:24

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 12

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

11 OCT 2020 01:45

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 13

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 11 OCT 2020 18:47

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 14

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 12 OCT 2020 15:39

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 15

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 16

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

14 OCT 2020 16:50

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 17

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 15 OCT 2020 14:21

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 18

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 19

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 18 OCT 2020 11:33

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(20)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 20

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 21

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 19 OCT 2020 16:20

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(22)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 22

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 23

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 21 OCT 2020 14:09

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 24

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

22 OCT 2020 13:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 25

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

24 OCT 2020 03:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 26

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

24 OCT 2020 12:00

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 27

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 25 OCT 2020 22:01

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 28

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 26 OCT 2020 13:00

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 29

Select one response below to indicate the level of your

None ☒

NAUSEA/VOMITING

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

27 OCT 2020 18:35

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 OCT 2020 12:46
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 OCT 2020 16:17
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 OCT 2020 06:23
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 01:44
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 18:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 OCT 2020 15:39
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 15

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 OCT 2020 16:50
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 14:21
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 OCT 2020 11:34
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 20

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	19 OCT 2020 16:20
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 22

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

21 OCT 2020 14:09

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	22 OCT 2020 13:12
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 25

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

No ☐

Yes ☒

PC Time stamp

24 OCT 2020 03:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 OCT 2020 12:00
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 OCT 2020 22:01
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 OCT 2020 13:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	27 OCT 2020 18:35
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3572134

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

28 OCT 2020 10:30

US3572134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	06 NOV 2020 11:41:19
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	22 NOV 2020 15:14:10
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 DEC 2020 00:01

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24 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

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31 MAR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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14 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

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21 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 APR 2022 00:01

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28 APR 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

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26 MAY 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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23 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

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14 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

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18 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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01 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted?

Yes ☒

No ☐

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

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572134

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572134

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572134

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:37:11

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 ☐

US3572134

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:37:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3572134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

AEID	
Adverse event	NAUSEA
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)	17 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)	17 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	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)	390 of 1978

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

AEID	
Adverse event	VOMITING
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)	17 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)	17 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	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)	392 of 1978

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

AEID	
Adverse event	DIARRHEA
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)	17 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)	17 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	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)

394 of 1978

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	2 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	5 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)	396 of 1978

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

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	SUBJECT STATES SYMPTOM "COMES AND GOES."
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

AEID	USA-US091-2020-MRNA-1273-P30 1000003
Adverse event	FALL
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)	9 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	398 of 1978

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

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

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

SUBJECT CALLED CLINIC ON
11/09/2020 AND REPORTED
THAT HE FELL DURING THE
PREVIOUS NIGHT WHEN HE
GOT UP TO GO TO THE
RESTROOM. HE REPORTED HE
IS HOSPITALIZED AND BROKE
SOME BONES.

SUBJECT HAD COMPLAINED OF
NAUSEA ON 11/05/2020 AND
WAS SCHEDULED FOR EVAL AT
THE RESEARCH SITE FOR
POSSIBLE COVID SWAB.
SUBJECT DID NOT STAY AT
CLINIC TO BE EVALUATED,
AND LEFT TO GO TO WORK.
SUBJECT WAS CONTACTED
AND RESCHEDULED TO BE AT
CLINIC ON 11/09/2020. HE
CALLED INSTEAD AND
NOTIFIED RESEARCH SITE
THAT HE WAS IN THE
HOSPITAL DUE TO A FALL
DURING THE NIGHT AND HAS A
LONG HISTORY OF DIZZINESS.
HOSPITAL RECORDS ARE
PENDING.

17 NOV 2020, SUBJECT CALLED
(b) (6) TO INFORM
DISCHARGE FROM HOSPITAL
ON 13 NOV 2020. SUBJECT WILL
BE SCHEDULED TO COME TO
SITE 18 NOV 2020, TO OBTAIN
RESEAL RECORD SIGNATURE.

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

US3572134

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:37:11

AEID	
Adverse event	
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)	
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	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
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	

US3572134

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:37:11

Congenital anomaly or birth defect		
Other medically important event		
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		
Concomitant Medication		
Concomitant Procedure		
Outcome	Fatal	☐
	Not Recovered/Not Resolved	☐
	Recovered/Resolved	☐
	Recovered/Resolved with Sequelae	☐
	Recovering/Resolving	☐
	Unknown	☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative		
Serious Adverse Event Derived (CSA Programming Field Only)		
Medically Attended AE Derived (CSA Programming Field Only)		
Admitted to ICU Derived (CSA Programming Field Only)		

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:11

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

Yes ☒

No ☐

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

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

Name of Medication	EXCEDRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3572134

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:37:11

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3572134

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3572134

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:37:11

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:11

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 21:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:11

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:11

SAEID	USA-US091-2020-MRNA-1273-P301000003
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/NOV/2020 11:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572134 (Prod: Laguna Clinical Research Associates)

US3572134

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:11

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3572134'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 16:59:18

US3572134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:29:06

US3572134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:59:19

US3572134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:29:06

US3572134

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 18:29:06

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:59:20

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Age](#)

Audit	User	Time (GMT)
User entered '48'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '48'	System	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

White

Audit	User	Time (GMT)
User closed query 'Race has not been provided. Please correct.' (Site from System).	System	28 Aug 2020 18:33:12
User entered '1' reason for change: Data Entry Error	Alisha Lutat (b) (4)	28 Aug 2020 18:33:12
User opened query 'Race has not been provided. Please correct.' (Site from System).	(b) (4)	
	System	28 Aug 2020 18:32:56
User entered '0'	Alisha Lutat (b) (4)	28 Aug 2020 18:32:56
	(b) (4)	

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:11

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:32:56

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:36

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:59:19

US3572134

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:26

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hypoglycaemic conditions NEC, PT: Hypoglycaemia, LLT: Hypoglycemia - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:35
Data point term sent to Coder	System	06 Nov 2020 00:32:49
User entered 'Hypoglycemia'	Alisha Lutat (b) (4)	06 Nov 2020 00:31:50
	(b) (4)	

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '2016'	System	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:31:50

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
Data point term sent to Coder	System	06 Nov 2020 00:32:49
User entered 'Insomnia'	Alisha Lutat (b) (4)	06 Nov 2020 00:32:21
	(b) (4)	

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Un UNK 2017'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:32:21

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
Data point term sent to Coder	System	06 Nov 2020 00:33:55
User entered 'Anxiety'	Alisha Lutat (b) (4)	06 Nov 2020 00:32:59
	(b) (4)	

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Un Aug 2019'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '2019'	System	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:32:59

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '12:20'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:20'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '73' in	Alisha Lutat (b) (4)	06 Nov 2020 00:49:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered '241.4' lb	Alisha Lutat (b) (4)	06 Nov 2020 00:49:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '31.91548'	System	06 Nov 2020 00:49:43
DataPoint set to visible.	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Nov 2020 00:49:43
DataPoint set to visible.	System	28 Aug 2020 18:35:44

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:49:43

US3572134

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3572134

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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 '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

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'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:04

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:17:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 18:36:00

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 17:39:49

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '109673'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 17:39:49

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 17:39:49

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

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 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:03:31
Query 'Per CDM: Please complete this section of the form.' answered with 'data updated ' (Site from DM).	Alisha Lutat (b) (4)	06 Nov 2020 00:51:32
User entered 'No (N)'	(b) (4)	
	Alisha Lutat (b) (4)	06 Nov 2020 00:51:23
	(b) (4)	
User opened query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 12:19:40

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:51:23

US3572134

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:11

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4)	06 Nov 2020 00:51:23
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:28:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:28:57

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:30'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:30'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Pulse (xxx)

Audit	User	Time (GMT)
User entered '93'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '153'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '102'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:11

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 00:58:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Nov 2020 00:58:57
User entered '13:46' reason for change: Data Entry Error	Alisha Lutat (b) (4)	06 Nov 2020 00:58:57
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 00:58:41
User entered empty.	Alisha Lutat (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:46'	System	06 Nov 2020 00:58:57
User entered empty.	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '93'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 00:58:41

US3572134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:05

US3572134

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:05

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 28Aug2020, however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:15:29
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28Aug2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:11:11
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:15'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:15'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 18:36:26

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:23'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:23'	System	06 Nov 2020 00:59:56

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:11

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:32'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:32'	System	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 01:00:21

US3572134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 17:40:03

US3572134

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:40:03

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:00:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered 'Yes (Y)'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:00:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered '97.7'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered 'No (N)'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e8f857ac-ba64-43de-8aa6-beb165d120cc'	System	28 Aug 2020 19:01:16
User entered '28 Aug 2020 14:01'	System	28 Aug 2020 19:01:16

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:42:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered 'Yes (Y)'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:42:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered '97.7'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered 'No (N)'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4862e11e-9f60-4def-8892-9e3e18a8e6e9'	System	29 Aug 2020 01:43:15
User entered '28 Aug 2020 20:43'	System	29 Aug 2020 01:43:15

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:42:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered 'Yes (Y)'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:42:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered '97.7'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered 'No (N)'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '30c54dc1-282b-4a76-91fc-d442c52d623d'	System	30 Aug 2020 03:43:10
User entered '29 Aug 2020 22:43'	System	30 Aug 2020 03:43:10

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:48:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered 'Yes (Y)'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:48:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered '97.7'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:49:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered 'No (N)'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:49:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ef3d39d8-62ef-46ef-9690-fb25af80b872'	System	30 Aug 2020 19:49:40
User entered '30 Aug 2020 14:49'	System	30 Aug 2020 19:49:40

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:21:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-eb413d37f832'	System	31 Aug 2020 17:26:04
User entered 'Yes (Y)'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-eb413d37f832'	System	31 Aug 2020 17:26:04
User entered '97.0'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-eb413d37f832'	System	31 Aug 2020 17:26:04
User entered 'No (N)'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:14', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fc1e96fb-4933-427d-9bbc-eb413d37f832'	System	31 Aug 2020 17:26:04
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 17:26:04

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:18:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered 'Yes (Y)'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered '97.5'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered 'No (N)'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a67aea59-fe7d-468f-8d53-3052ca2d85a7'	System	01 Sep 2020 18:19:21
User entered '01 Sep 2020 13:19'	System	01 Sep 2020 18:19:21

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:23:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered 'Yes (Y)'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:23:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered '97.9'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered 'No (N)'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '197b0aea-3317-44d1-8089-5854323a2342'	System	03 Sep 2020 00:24:11
User entered '02 Sep 2020 19:24'	System	03 Sep 2020 00:24:11

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered 'Yes (Y)'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered '97.3'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered 'No (N)'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '2100a542-3f52-4db6-8b70-8a3e0c6f9e7c'	System	03 Sep 2020 19:02:39
User entered '03 Sep 2020 14:02'	System	03 Sep 2020 19:02:39

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'None (1)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'No (N)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:01:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'No (N)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered 'None (1)'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '02ceab6d-f68b-4617-84bb-c0ae6d71cd83'	System	28 Aug 2020 19:02:32
User entered '28 Aug 2020 14:02'	System	28 Aug 2020 19:02:32

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'None (1)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'No (N)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'No (N)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered 'None (1)'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:43:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6820fcb8-d5c2-4094-b81b-f1d84c12c917'	System	29 Aug 2020 01:43:59
User entered '28 Aug 2020 20:43'	System	29 Aug 2020 01:43:59

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[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 (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'No (N)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'No (N)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-29T22:43:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered 'None (1)'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7d0cb01b-3720-4948-9361-311a7eed0507'	System	30 Aug 2020 03:44:05
User entered '29 Aug 2020 22:44'	System	30 Aug 2020 03:44:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'None (1)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'No (N)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'No (N)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered 'None (1)'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '43058c0b-d144-4bec-aade-7a8884bb3470'	System	30 Aug 2020 19:50:54
User entered '30 Aug 2020 14:50'	System	30 Aug 2020 19:50:54

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'None (1)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'No (N)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'No (N)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered 'None (1)'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:22:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0658e302-69d0-4013-a873-f79d9c34ab60'	System	31 Aug 2020 17:26:18
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 17:26:18

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[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 (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'None (1)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'No (N)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'No (N)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered 'None (1)'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a50c9629-a5e1-4eaf-9914-5ebfdc9bedcb'	System	01 Sep 2020 18:19:44
User entered '01 Sep 2020 13:19'	System	01 Sep 2020 18:19:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'None (1)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'No (N)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'No (N)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered 'None (1)'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:24:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fb8c0ff7-50a3-4dcb-92be-248936ec1f3f'	System	03 Sep 2020 00:24:44
User entered '02 Sep 2020 19:24'	System	03 Sep 2020 00:24:44

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[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 (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'None (1)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'No (N)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'No (N)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-03T14:02:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered 'None (1)'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51499f05-df46-4710-91ab-4758a8779db2'	System	03 Sep 2020 19:03:05
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:03:05

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:02:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'None (0)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered 'No (N)'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T14:03:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a61a307d-df45-420f-a264-4c8ba5d690f5'	System	28 Aug 2020 19:03:37
User entered '28 Aug 2020 14:03'	System	28 Aug 2020 19:03:37

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:35'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:05'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'None (0)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-28T20:44:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered 'No (N)'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-28T20:45:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '29e0dfd9-d2d0-4924-8bad-354211017b5f'	System	29 Aug 2020 01:45:06
User entered '28 Aug 2020 20:45'	System	29 Aug 2020 01:45:06

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 2'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:22', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'None (0)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered 'No (N)'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-29T22:44:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4c41cdb2-1401-4ffb-ac65-840959342d4f'	System	30 Aug 2020 03:44:54
User entered '29 Aug 2020 22:44'	System	30 Aug 2020 03:44:54

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 3'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:50:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:51:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'None (0)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-30T14:52:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered 'No (N)'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-30T14:52:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '50660cbe-2b80-43db-8201-40d95b71d8a9'	System	30 Aug 2020 19:52:18
User entered '30 Aug 2020 14:52'	System	30 Aug 2020 19:52:18

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 4'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'None (0)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered 'No (N)'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-08-31T12:23:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '761541e5-69c5-447a-a113-9c287a21cc5b'	System	31 Aug 2020 17:26:46
User entered '31 Aug 2020 12:23'	System	31 Aug 2020 17:26:46

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 5'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:19:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'No interference with activity (1)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'None (0)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered 'No (N)'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-01T13:20:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5e84b2be-d806-466a-8034-55d01dc8a6d5'	System	01 Sep 2020 18:20:56
User entered '01 Sep 2020 13:20'	System	01 Sep 2020 18:20:56

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 6'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:25:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'None (0)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered 'No (N)'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-02T19:26:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '17501c44-e7b1-4bf3-9219-2821f11b33e8'	System	03 Sep 2020 00:26:29
User entered '02 Sep 2020 19:26'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 7'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:14', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'None (0)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered 'No (N)'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-03T14:03:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd77fad5-5ed3-4ac0-84b3-1716603f057b'	System	03 Sep 2020 19:03:40
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 00:26:29
User entered 'Day 8'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '32c119a9-18ad-4282-b7e4-3a1a40b06a71'	System	04 Sep 2020 17:28:48
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '32c119a9-18ad-4282-b7e4-3a1a40b06a71'	System	04 Sep 2020 17:28:48
User entered '04 Sep 2020 12:28'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:03:40
User entered 'Day 9'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:45:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd746701-bc0c-4e27-b6b6-b62398ccbeed'	System	05 Sep 2020 17:46:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bd746701-bc0c-4e27-b6b6-b62398ccbeed'	System	05 Sep 2020 17:46:03
User entered '05 Sep 2020 12:46'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 17:28:48
User entered 'Day 10'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 17:46:03
User entered 'Day 11'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8144d87b-dd7a-443f-aedf-89474a29eaa1'	System	07 Sep 2020 22:48:14
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '8144d87b-dd7a-443f-aedf-89474a29eaa1'	System	07 Sep 2020 22:48:14
User entered '07 Sep 2020 17:48'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 22:48:14
User entered 'Day 12'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ffd060a8-6647-4f69-9819-bdd722cb68d0'	System	08 Sep 2020 21:32:42
User entered 'None (0)'	System	08 Sep 2020 21:32:42

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'ffd060a8-6647-4f69-9819-bdd722cb68d0'	System	08 Sep 2020 21:32:42
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 21:32:42

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 00:26:29
User entered 'Day 8'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-04T12:28:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4af29d69-d325-461c-812e-d6febabee6a1'	System	04 Sep 2020 17:29:09
User entered 'No (N)'	System	04 Sep 2020 17:29:09

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-04T12:29:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4af29d69-d325-461c-812e-d6febabee6a1'	System	04 Sep 2020 17:29:09
User entered '04 Sep 2020 12:29'	System	04 Sep 2020 17:29:09

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:26:29

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:03:40
User entered 'Day 9'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a95d6518-2791-464b-8fbc-3ae4882bb092'	System	05 Sep 2020 17:46:12
User entered 'No (N)'	System	05 Sep 2020 17:46:12

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-05T12:46:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a95d6518-2791-464b-8fbc-3ae4882bb092'	System	05 Sep 2020 17:46:12
User entered '05 Sep 2020 12:46'	System	05 Sep 2020 17:46:12

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:40

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 17:28:48
User entered 'Day 10'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:28:48

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 17:46:03
User entered 'Day 11'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b6f64581-4f0c-4d77-8117-0ecd573262aa'	System	07 Sep 2020 22:48:31
User entered 'No (N)'	System	07 Sep 2020 22:48:31

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-07T17:48:27', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b6f64581-4f0c-4d77-8117-0ecd573262aa'	System	07 Sep 2020 22:48:31
User entered '07 Sep 2020 17:48'	System	07 Sep 2020 22:48:31

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:46:03

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 22:48:14
User entered 'Day 12'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0177547f-8f6c-4dc0-8a66-af33fcc3f762'	System	08 Sep 2020 21:32:53
User entered 'No (N)'	System	08 Sep 2020 21:32:53

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-08T16:32:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0177547f-8f6c-4dc0-8a66-af33fcc3f762'	System	08 Sep 2020 21:32:53
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 21:32:53

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:48:14

US3572134

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:48:14

US3572134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 17:40:14

US3572134

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:40:14

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

US3572134

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:46

US3572134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:02:51

US3572134

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:02:51

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:35:56

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:35:56

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:35:56

US3572134

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:35:56

US3572134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:36:01

US3572134

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 21:36:01

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:26:49

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:26:49

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:26:49

US3572134

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	30 Sep 2020 12:26:49

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:10'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:10'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '102'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '20'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '134'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '91'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM: The treatment time on the Exposure CRF is 11:02 and the Vital Signs Post Dose Time of Assessment is 11:27 which has 25 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM). User entered '11:27'	(b) (4), (b) (6) Brett Potthoff (b) (4) (b) (4)	12 Nov 2020 06:38:52 30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:27'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '99'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '141'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '94'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:29:53

US3572134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:09

US3572134

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:09

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:02'	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:02'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 16:03:42

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:46'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:46'	System	30 Sep 2020 12:30:34

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:11

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '10:12'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:12'	System	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 12:30:52

US3572134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	30 Sep 2020 12:30:58

US3572134

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 12:30:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered 'Yes (Y)'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered '98.1'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered 'No (N)'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:35:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '03ff8106-5dd2-41cd-bc56-867babc5c15d'	System	29 Sep 2020 16:35:58
User entered '29 Sep 2020 11:35'	System	29 Sep 2020 16:35:58

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered 'Yes (Y)'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered '98.2'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered 'No (N)'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5afdeae6-71d9-43ee-a9ab-d17e0a04a103'	System	30 Sep 2020 04:08:38
User entered '29 Sep 2020 23:08'	System	30 Sep 2020 04:08:38

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered 'Yes (Y)'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered '98.2'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered 'No (N)'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a349d803-0f8b-41eb-8692-99220f895a6b'	System	01 Oct 2020 09:13:46
User entered '01 Oct 2020 04:13'	System	01 Oct 2020 09:13:46

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered 'Yes (Y)'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered '98.4'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:27:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered 'No (N)'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '57aabea7-b988-4666-8d85-2fdc53a68877'	System	02 Oct 2020 04:28:04
User entered '01 Oct 2020 23:28'	System	02 Oct 2020 04:28:04

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered 'Yes (Y)'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered '98.3'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered 'No (N)'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e66ae89-917d-4529-a775-6129188a47d3'	System	02 Oct 2020 17:49:45
User entered '02 Oct 2020 12:49'	System	02 Oct 2020 17:49:45

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:38:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered 'Yes (Y)'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered '98.5'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered 'No (N)'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bfab12d9-f337-4153-b6e9-67511d21fe2a'	System	03 Oct 2020 22:39:13
User entered '03 Oct 2020 17:39'	System	03 Oct 2020 22:39:13

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:23:59', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered 'Yes (Y)'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered '97.2'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered 'No (N)'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '98bfba38-417f-42d8-9a9a-e3f5639a58ed'	System	04 Oct 2020 22:24:16
User entered '04 Oct 2020 17:24'	System	04 Oct 2020 22:24:16

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'None (1)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'No (N)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'No (N)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered 'None (1)'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:33', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0998d1f6-9257-4f2b-9c2e-38b76e0a08e9'	System	29 Sep 2020 16:36:38
User entered '29 Sep 2020 11:36'	System	29 Sep 2020 16:36:38

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T23:08:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'None (1)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'No (N)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'No (N)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered 'None (1)'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0623fed3-b06d-4a66-8404-6ad35250f1f4'	System	30 Sep 2020 04:09:29
User entered '29 Sep 2020 23:09'	System	30 Sep 2020 04:09:29

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'None (1)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:13:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'No (N)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'No (N)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered 'None (1)'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7e94aab6-5d92-4b5d-b6a4-38f5a14200b4'	System	01 Oct 2020 09:14:16
User entered '01 Oct 2020 04:14'	System	01 Oct 2020 09:14:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[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 (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'None (1)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'No (N)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'No (N)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered 'None (1)'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '454cb6dc-36fb-45aa-a800-906c5bce4ec0'	System	02 Oct 2020 04:28:31
User entered '01 Oct 2020 23:28'	System	02 Oct 2020 04:28:31

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'None (1)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:49:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'No (N)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'No (N)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered 'None (1)'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '431fd288-0f29-4295-a6d0-577d12740152'	System	02 Oct 2020 17:50:16
User entered '02 Oct 2020 12:50'	System	02 Oct 2020 17:50:16

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcf567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'None (1)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcfe567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'No (N)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcfe567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'No (N)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcfe567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered 'None (1)'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:39:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fdcf567-bedd-4c9c-bee4-50524fa09480'	System	03 Oct 2020 22:39:50
User entered '03 Oct 2020 17:39'	System	03 Oct 2020 22:39:50

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'None (1)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'No (N)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:24:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'No (N)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered 'None (1)'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'bcfe9274-27f7-4674-92bf-e5dbaeba3ef5'	System	04 Oct 2020 22:25:04
User entered '04 Oct 2020 17:25'	System	04 Oct 2020 22:25:04

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:36:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'None (0)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered 'No (N)'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T11:37:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '6e797fcf-b008-4e66-9c7b-35a4d63009df'	System	29 Sep 2020 16:37:52
User entered '29 Sep 2020 11:37'	System	29 Sep 2020 16:37:52

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:52'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:09:55', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'None (0)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered 'No (N)'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-09-29T23:10:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'debae378-8a86-44fe-8ccb-def8d04afc4b'	System	30 Sep 2020 04:10:34
User entered '29 Sep 2020 23:10'	System	30 Sep 2020 04:10:34

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:47'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 2'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:34', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:48', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'None (0)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-01T04:14:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered 'No (N)'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T04:15:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4d2d95e2-f339-47ea-aec4-9663ba5568b5'	System	01 Oct 2020 09:15:08
User entered '01 Oct 2020 04:15'	System	01 Oct 2020 09:15:08

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 3'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:40', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:28:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'None (0)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered 'No (N)'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-01T23:29:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b9abcd94-5656-4e2b-b8c6-85dee8486c87'	System	02 Oct 2020 04:29:19
User entered '01 Oct 2020 23:29'	System	02 Oct 2020 04:29:19

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 4'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:50:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'None (0)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-02T12:51:01', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered 'No (N)'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-02T12:51:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'aba7ed7f-0bdf-4bb0-a84e-117091401daf'	System	02 Oct 2020 17:51:07
User entered '02 Oct 2020 12:51'	System	02 Oct 2020 17:51:07

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 5'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'None (0)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-03T17:40:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered 'No (N)'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-03T17:41:02', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'd49436b6-eedc-4fc4-ac76-a454daa50436'	System	03 Oct 2020 22:41:14
User entered '03 Oct 2020 17:41'	System	03 Oct 2020 22:41:14

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 6'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:18', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'None (0)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-04T17:25:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered 'No (N)'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-04T17:26:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c76e5a-b889-49e7-94a3-247e373a61a0'	System	04 Oct 2020 22:26:01
User entered '04 Oct 2020 17:26'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:03:42
User entered 'Day 7'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:03:42

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:26', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cd3aced5-8172-4164-a39a-255a14633482'	System	06 Oct 2020 17:47:35
User entered 'None (0)'	System	06 Oct 2020 17:47:35

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cd3aced5-8172-4164-a39a-255a14633482'	System	06 Oct 2020 17:47:35
User entered '06 Oct 2020 12:47'	System	06 Oct 2020 17:47:35

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '01d3de56-2296-4337-bfe1-e8ac9b7ed577'	System	06 Oct 2020 17:47:18
User entered 'None (0)'	System	06 Oct 2020 17:47:18

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:47:11', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '01d3de56-2296-4337-bfe1-e8ac9b7ed577'	System	06 Oct 2020 17:47:18
User entered '06 Oct 2020 12:47'	System	06 Oct 2020 17:47:18

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '94b93e8e-6353-46eb-93fb-a59b14ed4403'	System	06 Oct 2020 17:46:55
User entered 'None (0)'	System	06 Oct 2020 17:46:55

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '94b93e8e-6353-46eb-93fb-a59b14ed4403'	System	06 Oct 2020 17:46:55
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:55

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:31', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'de791a24-2177-4ab6-8331-8f70d163c8b5'	System	06 Oct 2020 17:46:40
User entered 'None (0)'	System	06 Oct 2020 17:46:40

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:37', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'de791a24-2177-4ab6-8331-8f70d163c8b5'	System	06 Oct 2020 17:46:40
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:40

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '55a7ccfd-afd5-4420-9fee-745003e63a06'	System	06 Oct 2020 17:46:31
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '55a7ccfd-afd5-4420-9fee-745003e63a06'	System	06 Oct 2020 17:46:31
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 9'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-07T15:28:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7a8dec2-5b99-4c34-9acb-11246eaf8ce6'	System	07 Oct 2020 20:28:09
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-07T15:28:05', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '7a8decd2-5b99-4c34-9acb-11246eaf8ce6'	System	07 Oct 2020 20:28:09
User entered '07 Oct 2020 15:28'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 10'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:18:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '3791496a-966e-4c9e-a9b0-36ee66c28781'	System	08 Oct 2020 21:18:12
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:18:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '3791496a-966e-4c9e-a9b0-36ee66c28781'	System	08 Oct 2020 21:18:12
User entered '08 Oct 2020 16:18'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:28:09
User entered 'Day 11'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:24:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c69be7-1c13-4b9a-b651-1c66c4bc3ec9'	System	10 Oct 2020 11:24:11
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:24:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e1c69be7-1c13-4b9a-b651-1c66c4bc3ec9' User entered '10 Oct 2020 06:24'	System	10 Oct 2020 11:24:11
	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 21:18:12
User entered 'Day 12'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:45:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1934476d-9ed6-4a8c-887c-4f9ced427913'	System	11 Oct 2020 06:45:15
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:45:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1934476d-9ed6-4a8c-887c-4f9ced427913'	System	11 Oct 2020 06:45:15
User entered '11 Oct 2020 01:45'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 11:24:11
User entered 'Day 13'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:04', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b59ddc09-aaa4-47b8-b1c6-fb0875ae1fdf'	System	11 Oct 2020 23:47:10
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b59ddc09-aaa4-47b8-b1c6-fb0875ae1fdf'	System	11 Oct 2020 23:47:10
User entered '11 Oct 2020 18:47'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 06:45:15
User entered 'Day 14'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '11bc627c-f9b4-4ff4-bfbe-3a997a07e3c3'	System	12 Oct 2020 20:39:47
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '11bc627c-f9b4-4ff4-bfbe-3a997a07e3c3'	System	12 Oct 2020 20:39:47
User entered '12 Oct 2020 15:39'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 23:47:10
User entered 'Day 15'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 20:39:47
User entered 'Day 16'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51768654-d6da-49b3-9a35-4488fa76e89e'	System	14 Oct 2020 21:50:32
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:29', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '51768654-d6da-49b3-9a35-4488fa76e89e'	System	14 Oct 2020 21:50:32
User entered '14 Oct 2020 16:50'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 17'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:07', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9faa4696-6613-4a76-98f9-72d6567a56e3'	System	15 Oct 2020 19:21:16
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:13', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9faa4696-6613-4a76-98f9-72d6567a56e3'	System	15 Oct 2020 19:21:16
User entered '15 Oct 2020 14:21'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 18'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:21:16
User entered 'Day 19'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fbfe020e-9150-4ae6-9232-c0fe0f8fbb16'	System	18 Oct 2020 16:33:55
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'fbfe020e-9150-4ae6-9232-c0fe0f8fbb16'	System	18 Oct 2020 16:33:55
User entered '18 Oct 2020 11:33'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(20)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 20'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(20)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(20)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 21'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:03', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a4b18397-fd42-4872-aeab-0bd61b96ceaf'	System	19 Oct 2020 21:20:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:09', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a4b18397-fd42-4872-aeab-0bd61b96ceaf'	System	19 Oct 2020 21:20:15
User entered '19 Oct 2020 16:20'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(22)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 22'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(22)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(22)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 23'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:28', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a8118ea9-aac0-44c2-93aa-6aa23c598560'	System	21 Oct 2020 19:09:39
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a8118ea9-aac0-44c2-93aa-6aa23c598560'	System	21 Oct 2020 19:09:39
User entered '21 Oct 2020 14:09'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 24'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '73f568fc-b655-49de-afd5-ae4d69b61f93'	System	22 Oct 2020 18:12:37
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:30', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '73f568fc-b655-49de-afd5-ae4d69b61f93'	System	22 Oct 2020 18:12:37
User entered '22 Oct 2020 13:12'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 25'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c162f6a3-8f54-48d2-be73-893a8c00a37e'	System	24 Oct 2020 08:43:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c162f6a3-8f54-48d2-be73-893a8c00a37e'	System	24 Oct 2020 08:43:50
User entered '24 Oct 2020 03:43'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 18:12:37
User entered 'Day 26'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cc612f58-dccf-4370-a839-f9b720cc098c'	System	24 Oct 2020 17:00:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'cc612f58-dccf-4370-a839-f9b720cc098c'	System	24 Oct 2020 17:00:52
User entered '24 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 08:43:50
User entered 'Day 27'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1c608be3-a8fe-4b18-a9a0-c56ebcbabb1f'	System	26 Oct 2020 03:01:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:38', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1c608be3-a8fe-4b18-a9a0-c56ebcbabb1f'	System	26 Oct 2020 03:01:41
User entered '25 Oct 2020 22:01'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 17:00:52
User entered 'Day 28'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5bc02eaf-8238-47ee-bef4-5a12a05dde04'	System	26 Oct 2020 18:00:46
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	26 Oct 2020 18:00:46

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '5bc02eaf-8238-47ee-bef4-5a12a05dde04'	System	26 Oct 2020 18:00:46
User entered '26 Oct 2020 13:00'	System	26 Oct 2020 18:00:46

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 03:01:41
User entered 'Day 29'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9bbbcfd5-1313-4fd7-9d8a-8b67f50724e7'	System	27 Oct 2020 23:35:43
User entered 'None (0)'	System	27 Oct 2020 23:35:43

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '9bbbcfd5-1313-4fd7-9d8a-8b67f50724e7'	System	27 Oct 2020 23:35:43
User entered '27 Oct 2020 18:35'	System	27 Oct 2020 23:35:43

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Nausea_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 22:26:01
User entered 'Day 8'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-06T12:45:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b271f1d1-401f-4216-8ce2-6b34999a6672'	System	06 Oct 2020 17:46:13
User entered 'No (N)'	System	06 Oct 2020 17:46:13

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-06T12:46:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b271f1d1-401f-4216-8ce2-6b34999a6672'	System	06 Oct 2020 17:46:13
User entered '06 Oct 2020 12:46'	System	06 Oct 2020 17:46:13

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 22:26:01

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 17:46:31
User entered 'Day 10'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-08T16:17:54', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '342f2bb3-13f9-44c2-a5b7-ee2f03b314cf'	System	08 Oct 2020 21:18:00
User entered 'No (N)'	System	08 Oct 2020 21:18:00

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-08T16:17:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '342f2bb3-13f9-44c2-a5b7-ee2f03b314cf'	System	08 Oct 2020 21:18:00
User entered '08 Oct 2020 16:17'	System	08 Oct 2020 21:18:00

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:46:31

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:28:09
User entered 'Day 11'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-10T06:23:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'dc713972-1af2-419c-a9f5-40e86a13ba43'	System	10 Oct 2020 11:23:59
User entered 'No (N)'	System	10 Oct 2020 11:23:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-10T06:23:58', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'dc713972-1af2-419c-a9f5-40e86a13ba43'	System	10 Oct 2020 11:23:59
User entered '10 Oct 2020 06:23'	System	10 Oct 2020 11:23:59

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:28:09

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 21:18:12
User entered 'Day 12'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-11T01:44:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c9b743d0-80ea-48e2-96bb-d55a26b788f9'	System	11 Oct 2020 06:44:58
User entered 'No (N)'	System	11 Oct 2020 06:44:58

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T01:44:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'c9b743d0-80ea-48e2-96bb-d55a26b788f9'	System	11 Oct 2020 06:44:58
User entered '11 Oct 2020 01:44'	System	11 Oct 2020 06:44:58

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:18:12

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 11:24:11
User entered 'Day 13'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:17', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '63938cba-d77d-4634-a2bd-3093591ae786'	System	11 Oct 2020 23:47:23
User entered 'No (N)'	System	11 Oct 2020 23:47:23

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-11T18:47:20', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '63938cba-d77d-4634-a2bd-3093591ae786'	System	11 Oct 2020 23:47:23
User entered '11 Oct 2020 18:47'	System	11 Oct 2020 23:47:23

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 11:24:11

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 06:45:15
User entered 'Day 14'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:51', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '000869d6-26f1-4394-888d-69d050f6e943'	System	12 Oct 2020 20:39:54
User entered 'No (N)'	System	12 Oct 2020 20:39:54

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-12T15:39:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '000869d6-26f1-4394-888d-69d050f6e943'	System	12 Oct 2020 20:39:54
User entered '12 Oct 2020 15:39'	System	12 Oct 2020 20:39:54

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 06:45:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 23:47:10
User entered 'Day 15'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 23:47:10

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 20:39:47
User entered 'Day 16'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e0d2b8f1-9fd3-40b1-b725-f9e3765e7e88'	System	14 Oct 2020 21:50:43
User entered 'No (N)'	System	14 Oct 2020 21:50:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-14T16:50:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'e0d2b8f1-9fd3-40b1-b725-f9e3765e7e88'	System	14 Oct 2020 21:50:43
User entered '14 Oct 2020 16:50'	System	14 Oct 2020 21:50:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:39:47

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 17'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:21', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b1dbc19e-4d3d-4583-aecb-58d79c79b7c1'	System	15 Oct 2020 19:21:27
User entered 'No (N)'	System	15 Oct 2020 19:21:27

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-15T14:21:24', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'b1dbc19e-4d3d-4583-aecb-58d79c79b7c1'	System	15 Oct 2020 19:21:27
User entered '15 Oct 2020 14:21'	System	15 Oct 2020 19:21:27

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 21:50:32
User entered 'Day 18'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:50:32

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:21:16
User entered 'Day 19'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-18T11:33:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'df2b48c9-0aa6-44f1-80a9-fe3b3a6c1c7f'	System	18 Oct 2020 16:34:04
User entered 'No (N)'	System	18 Oct 2020 16:34:04

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-18T11:34:00', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'df2b48c9-0aa6-44f1-80a9-fe3b3a6c1c7f'	System	18 Oct 2020 16:34:04
User entered '18 Oct 2020 11:34'	System	18 Oct 2020 16:34:04

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:21:16

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 20'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 16:33:55
User entered 'Day 21'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:16', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '48390f98-62af-44ff-9f40-2473ec296835'	System	19 Oct 2020 21:20:24
User entered 'Yes (Y)'	System	19 Oct 2020 21:20:24

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-19T16:20:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '48390f98-62af-44ff-9f40-2473ec296835'	System	19 Oct 2020 21:20:24
User entered '19 Oct 2020 16:20'	System	19 Oct 2020 21:20:24

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 16:33:55

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 22'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:20:15
User entered 'Day 23'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:43', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35f1ad56-1983-473f-93c2-9b4a66accb36'	System	21 Oct 2020 19:09:50
User entered 'No (N)'	System	21 Oct 2020 19:09:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-21T14:09:46', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '35f1ad56-1983-473f-93c2-9b4a66accb36'	System	21 Oct 2020 19:09:50
User entered '21 Oct 2020 14:09'	System	21 Oct 2020 19:09:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:20:15

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 24'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:36', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '40dc99c9-b1ef-48d1-bd46-93a78da7426a'	System	22 Oct 2020 18:12:43
User entered 'Yes (Y)'	System	22 Oct 2020 18:12:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-22T13:12:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '40dc99c9-b1ef-48d1-bd46-93a78da7426a'	System	22 Oct 2020 18:12:43
User entered '22 Oct 2020 13:12'	System	22 Oct 2020 18:12:43

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:09:39
User entered 'Day 25'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '996e7b6d-5885-4fce-84ce-8c5c0fac9446'	System	24 Oct 2020 08:43:56
User entered 'Yes (Y)'	System	24 Oct 2020 08:43:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T03:43:53', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '996e7b6d-5885-4fce-84ce-8c5c0fac9446'	System	24 Oct 2020 08:43:56
User entered '24 Oct 2020 03:43'	System	24 Oct 2020 08:43:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:09:39

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 18:12:37
User entered 'Day 26'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:50', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '64663a4d-51ee-42c4-954e-df0e50e363b7'	System	24 Oct 2020 17:00:56
User entered 'No (N)'	System	24 Oct 2020 17:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-24T12:00:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '64663a4d-51ee-42c4-954e-df0e50e363b7'	System	24 Oct 2020 17:00:56
User entered '24 Oct 2020 12:00'	System	24 Oct 2020 17:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:12:37

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 08:43:50
User entered 'Day 27'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:42', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4f0cebe7-c65e-4a7a-b22c-343f1db712cc'	System	26 Oct 2020 03:01:49
User entered 'No (N)'	System	26 Oct 2020 03:01:49

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-25T22:01:45', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '4f0cebe7-c65e-4a7a-b22c-343f1db712cc'	System	26 Oct 2020 03:01:49
User entered '25 Oct 2020 22:01'	System	26 Oct 2020 03:01:49

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 08:43:50

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 17:00:52
User entered 'Day 28'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:49', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '81bcfa6c-ce96-4403-aade-7628825a8b18'	System	26 Oct 2020 18:00:56
User entered 'No (N)'	System	26 Oct 2020 18:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-26T13:00:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '81bcfa6c-ce96-4403-aade-7628825a8b18'	System	26 Oct 2020 18:00:56
User entered '26 Oct 2020 13:00'	System	26 Oct 2020 18:00:56

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:00:52

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 03:01:41
User entered 'Day 29'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

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 (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:44', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0008b906-68f6-4a01-a876-c912d715633f'	System	27 Oct 2020 23:35:51
User entered 'No (N)'	System	27 Oct 2020 23:35:51

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-27T18:35:47', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '0008b906-68f6-4a01-a876-c912d715633f'	System	27 Oct 2020 23:35:51
User entered '27 Oct 2020 18:35'	System	27 Oct 2020 23:35:51

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 03:01:41

US3572134

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:37:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 03:01:41

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 22:32:21

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 22:32:21

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Mcdowell (b) (4)	06 Oct 2020 22:32:21

US3572134

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 22:32:21

US3572134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 22:32:27

US3572134

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:32:27

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	13 Oct 2020 21:55:42

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Jessica Mcdowell (b) (4) (b) (4)	13 Oct 2020 21:55:42

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Mcdowell (b) (4)	13 Oct 2020 21:55:42

US3572134

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	13 Oct 2020 21:55:42

US3572134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	13 Oct 2020 21:55:54

US3572134

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:55:54

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	20 Oct 2020 16:50:02

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Jessica Mcdowell (b) (4) (b) (4)	20 Oct 2020 16:50:02

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Mcdowell (b) (4)	20 Oct 2020 16:50:02

US3572134

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	20 Oct 2020 16:50:02

US3572134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	20 Oct 2020 16:51:01

US3572134

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 16:51:01

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Nov 2020 01:02:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:07:35

US3572134

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:07:35

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:30'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:12

US3572134

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 10:30'	System	06 Nov 2020 01:08:12

US3572134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 01:08:18

US3572134

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 01:08:18

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 64'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'Yes (Y)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:25', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'No (N)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:35', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'No (N)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:13:56', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'Yes (Y)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:14:08', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-10-28T10:14:12', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '41b6957c-cb48-4a1c-b887-19eb23d6f2e3'	System	28 Oct 2020 15:14:23
User entered '28 Oct 2020 10:14:12'	System	28 Oct 2020 15:14:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered 'Day 71'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:40:39', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'Yes (Y)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:40:52', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:15', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered 'No (N)'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-06T11:41:19', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: 'a5d854f5-b8d5-43f3-9176-de920992578a'	System	06 Nov 2020 17:41:23
User entered '06 Nov 2020 11:41:19'	System	06 Nov 2020 17:41:23

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 18:36:26

US3572134

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 18:36:26
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 18:36:26

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:23', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'Yes (Y)'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:32', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'No (N)'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:41', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'No (N)'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:13:57', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'Yes (Y)'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:14:06', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09ef9a7cf96a439e)', Time: '2020-11-22T15:14:10', User OID: 'PatientReportedOutcome (US3572134)', ODM File OID: '1f97f653-1cd5-49f2-bb01-3a13d8fac506'	System	22 Nov 2020 21:14:20
User entered '22 Nov 2020 15:14:10'	System	22 Nov 2020 21:14:20

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:57:54

US3572134

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:57:54
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:57:54

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	23 Nov 2020 15:25:11

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Jessica Mcdowell (b) (4) (b) (4)	23 Nov 2020 15:25:11

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Mcdowell (b) (4)	23 Nov 2020 15:25:11

US3572134

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	23 Nov 2020 15:25:11

US3572134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	23 Nov 2020 15:25:01

US3572134

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 15:25:01

US3572134

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	11 Sep 2020 18:03:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
Data point term sent to Coder	System	18 Sep 2020 21:51:13
User entered 'nausea'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:11:06
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' answered with 'Data updated ' (Site from DM).	Maria Candelario (b) (4)	17 Nov 2020 15:55:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 15:54:57
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:31
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 15:54:57
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:54:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 21:50:29
User entered '05:00'	Jasmine Ali (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:54:57
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Nov 2020 15:55:37
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:55:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Sep 2020 21:50:29
User entered '14:00'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:55:37
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:50:29
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:50:29
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:54:57
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:50:29
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:50:29

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:51:41
Data point term sent to Coder	System	18 Sep 2020 21:51:14
User entered 'vomiting'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:11:23
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4)	17 Nov 2020 15:57:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 15:56:54
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:45
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 15:56:54
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 21:51:04
User entered '05:00'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:56:54
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Nov 2020 15:56:54
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Sep 2020 21:51:04
User entered '14:00'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:56:54
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:04
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:04
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:04
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:56:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:56:54
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:56:54
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:04
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 15:56:54

US3572134

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:51:04

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:53:39
Data point term sent to Coder	System	18 Sep 2020 21:52:17
User entered 'diarrhea'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:11:34
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Data Updated' (Site from DM).	Maria Candelario (b) (4)	17 Nov 2020 16:12:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 15:58:17
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:23:52
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 15:58:17
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:58:17
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 21:51:31
User entered '05:00'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:58:17
User entered '17 Sep 2020 05:00'	System	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Nov 2020 15:58:17
User entered empty; reason for change Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:58:17
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Sep 2020 21:51:31
User entered '14:00'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:58:17
User entered '17 Sep 2020 14:00'	System	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:00:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 16:00:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 16:00:27
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:31
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:58:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:58:17
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:31
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 15:58:17
User entered 'None (NONE)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:58:17
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:51:31
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:51:31

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
Data point term sent to Coder	System	06 Oct 2020 23:22:28
User entered 'diarrhea'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:23:16
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4)	17 Nov 2020 16:13:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 16:12:55
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:38
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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	24 Nov 2020 17:23:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Nov 2020 17:23:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 17:21:33
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User entered empty.	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:23:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:01:55
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:21:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:23:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject states symptom "comes and goes."'	Jessica Mcdowell (b) (4)	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 23:22:20

US3572134

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 23:22:20

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:29:07
User entered 'USA-US091-2020-mRNA-1273-P301000003'	System	10 Nov 2020 21:13:58
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 21:13:58

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:51:38
Data point term sent to Coder	System	10 Nov 2020 18:35:54
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 18:35:27
User entered 'Fall' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:35:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 10:52:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 10:52:30
Data point term sent to Coder	System	09 Nov 2020 23:00:12
User entered 'Initial SAE report, Pending medical records	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10
Fall'		

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:36
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:34
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:33
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:31
User entered '9 Nov 2020'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:29
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:28
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 15:38:04
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:38:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 15:37:43
User entered 'Yes (Y)'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:26
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 15:37:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 15:37:43
User entered '13 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4)	17 Nov 2020 15:37:43
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 15:37:07
User entered empty.	Maria Candelario (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:24
User entered empty.	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Nov 2020 18:36:52
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Nov 2020 23:00:10
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:16
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:15
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:13
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 05:30:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject was admitted to the hospital on 11/09/2020 (per subject) and is still in the hospital. Records are pending.' (Site from System).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		10 Nov 2020 18:36:52
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 18:36:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Nov 2020 18:36:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:36:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Nov 2020 23:00:10
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:10:11
User entered '9 Nov 2020'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:11
User entered '13 Nov 2020' reason for change: Data Entry Error	Maria Candelario (b) (4)	18 Nov 2020 00:49:18
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:07
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:06
User entered empty.	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:04
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:02
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:09:00
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:59
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:29:13
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:47
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:43:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:57
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:29:14
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:27:45
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:43:43
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 02:38:36
	(b) (4), (b) (6)	25 Nov 2020 02:36:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 02:36:57
User opened query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:21:24
	(b) (4), (b) (6)	18 Nov 2020 13:08:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'None (NONE)' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4)	09 Nov 2020 23:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Nov 2020 15:26:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 23:00:10
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:49
User entered '1' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
User entered '0'	Maria Candelario (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:47
User entered '1' reason for change: Data Entry Error	Milton Haber (b) (4)	11 Nov 2020 15:26:47
User entered '0'	(b) (4) Maria Candelario (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	17 Nov 2020 15:37:07
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:26:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	11 Nov 2020 15:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:43
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:49:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:19
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:11
Query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:48:02
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 02:39:43
User opened query 'PV Query: Please confirm if broken bones or injuries sustained from fall should be added as SAEs.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:35

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:24:09
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:23:23
User opened query 'PV Query: Please confirm if dizziness is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:22:33
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 20:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:08:42

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES. SUBJECT HAD COMPLAINED OF NAUSEA ON 11/05/2020 AND WAS SCHEDULED FOR EVAL AT THE RESEARCH SITE FOR POSSIBLE COVID SWAB. SUBJECT DID NOT STAY AT CLINIC TO BE EVALUATED, AND LEFT TO GO TO WORK. SUBJECT WAS CONTACTED AND RESCHEDULED TO BE AT CLINIC ON 11/09/2020. HE CALLED INSTEAD AND NOTIFIED RESEARCH SITE THAT HE WAS IN THE HOSPITAL DUE TO A FALL DURING THE NIGHT AND HAS A LONG HISTORY OF DIZZINESS. HOSPITAL RECORDS ARE PENDING. 17 NOV 2020, SUBJECT CALLED (b) (6) TO INFORM DISCHARGE FROM HOSPITAL ON 13 NOV 2020. SUJECT WILL BE SCHEDULED TO COME TO SITE 18 NOV 2020, TO OBTAIN RESEALE RECORD SIGNATURE.' reason for change: Data Entry Error	Maria Candelario (b) (4)	18 Nov 2020 00:51:33
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.	Milton Haber (b) (4)	11 Nov 2020 15:26:47

Subject had complained of nausea on 11/05/2020 and was scheduled for eval at the research site for possible Covid swab. Subject did not stay at clinic to be evaluated, and left to go to work. Subject was contacted and rescheduled to be at clinic on 11/09/2020. He called instead and notified research site that he was in the hospital due to a fall during the night and has a long history of dizziness. Hospital records are pending.' reason for change: Data Entry Error

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED CLINIC ON 11/09/2020 AND REPORTED THAT HE FELL DURING THE PREVIOUS NIGHT WHEN HE GOT UP TO GO TO THE RESTROOM. HE REPORTED HE IS HOSPITALIZED AND BROKE SOME BONES.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:37:28
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 18:36:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 18:36:52
User entered 'Subject called clinic on 11/10/2020 and reported that he fell during the previous night when he got up to go to the restroom. He reported he is hospitalized and broke some bones.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:36:52
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 23:00:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 23:00:10

US3572134

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 23:00:10

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:53:40

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:41
Data point term sent to Coder	System	23 Sep 2020 23:04:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:03:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:03:39
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' canceled (Site from System).	Coder Import (b) (4)	23 Sep 2020 23:03:38
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	21 Sep 2020 11:51:37
Data point term sent to Coder	System	18 Sep 2020 21:54:20
User entered 'Excedrin'	Jasmine Ali (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:54:04

US3572134

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:54:04

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered '10/Nov/2020 21:14'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:11

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)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Nov/2020 14:30'	System	12 Nov 2020 14:30:53

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:11

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)	18 Nov 2020 16:44:11
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 14:30:53

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'USA-US091-2020-MRNA-1273-P301000003'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'No (N)'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Milton'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Haber'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '2344 Laguna Del Mar, Suite 201'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'Laredo'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered 'TX'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:14:12
User entered '78041'	System	10 Nov 2020 21:13:58

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:30:28
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
User entered 'US'	(b) (4) System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 16:44:26
Signature has been broken.	System	12 Nov 2020 14:30:53
User entered '2'	System	12 Nov 2020 14:30:53
User signature succeeded.	Milton Haber (b) (4)	11 Nov 2020 15:17:23
	(b) (4)	
User entered '1'	System	10 Nov 2020 21:14:19

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 11:44'	System	18 Nov 2020 16:44:26

US3572134

Folder: SAE USA-US091-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 16:44:26